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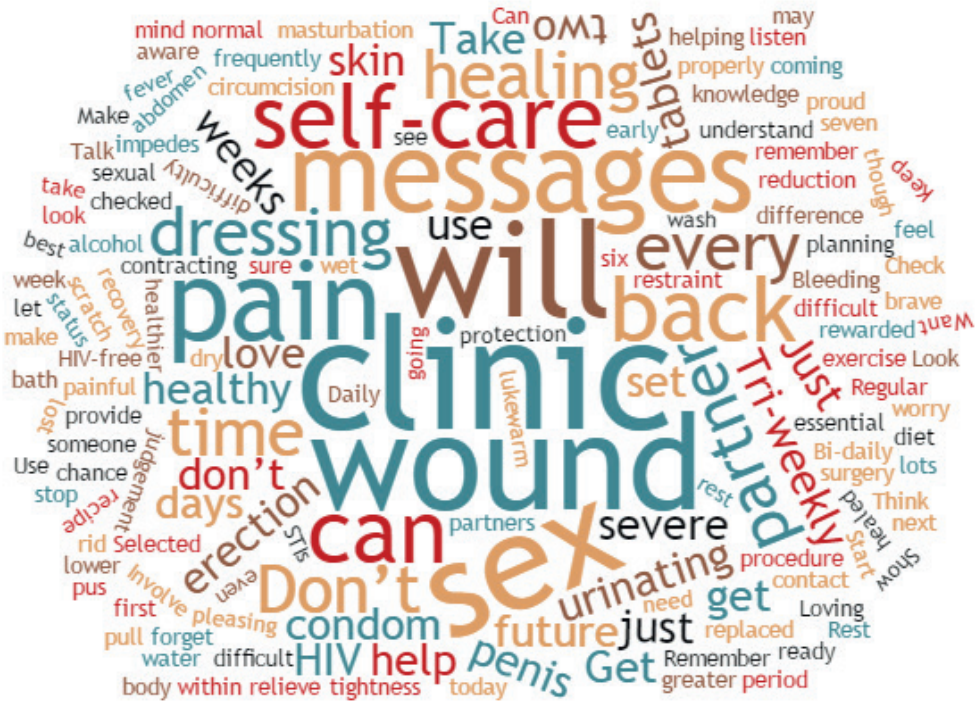
Development and testing of an m-health platform to reduce post-operative penetrative sex in recipients of voluntary medical male circumcision



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DEVELOPMENT AND TESTING OF AN M-HEALTH PLATFORM TO REDUCE POST-OPERATIVE PENETRATIVE SEX IN RECIPIENTS OF VOLUNTARY MEDICAL MALE CIRCUMCISION

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DEVELOPMENT AND TESTING OF AN M-HEALTH PLATFORM TO REDUCE POST-OPERATIVE PENETRATIVE SEX IN RECIPIENTS OF VOLUNTARY MEDICAL MALE CIRCUMCISION

THESIS FOR DOCTORAL DEGREE (Ph.D.)

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This thesis is dedicated to the men in the communities who generously gave of themselves to allowed me this body of work.

The artwork on the cover is a word-cloud generated from the messages the men and their partners suggested to be included in the m-Health intervention

ABSTRACT

Background: The widespread roll-out of voluntary medical male circumcision (VMMC) has been accompanied by reports of VMMC recipients, particularly men who are married or cohabiting, resuming sexual intercourse before the recommended healing period of six weeks. This behaviour carries an increased risk of transmission of STIs and HIV, particularly for the female partner. At the same time, it is unrealistic to assume that an already over-burdened health system will be able to provide repeated, intense messaging that recent recipients of VMMC may need to help them navigate the post-operative period sexually. There is an urgent need to develop culturally appropriate messages and innovative delivery strategies for behaviour modification in the post-operative period and the longer term for medically circumcised men.

Methods: As a step to better understand the behaviour of the VMMC patients during the six-week recovery period, we conducted eight single-gender focus groups with males who had undergone VMMC in the previous six months and their partners.(Study 1) Armed with this information, we strove to create a contextually-relevant message regime by using a staggered qualitative methodology: (1) focus group discussions with 52 recently circumcised men and their partners to develop initial voice messages (2) thematic analysis and expert consultation to select the final messages for pilot testing, and (3) cognitive interviews with 12 recent VMMC patients to judge message comprehension and rank the messages. The message content and phasing were guided by the theory of planned behaviour, the health action process approach and the action research approach. (Study 2) For the next two years, this intervention was evaluated using a two-armed, randomized, single-blind, controlled design. This sample was collected at 12 clinics in urban areas in Western Cape Province, South Africa. Patients were followed up at 42 days after enrolment. (Study 3) As a final measure, the usability of the platform was evaluated. At follow-up, 597 participants completed questionnaires regarding the usability and user experience of the mobile audio platform. Usability was measured with the System Usability Scale (SUS). Five focus groups with a total of 25 patients were also conducted. The scale's multidimensionality was shown with the emergence of three trends that explained more than 65% of the total variance of the scale. (Study 4)

Results: The primary motivation to VMMC uptake included religious injunction and hygiene reasons and protection against sexually transmitted infections not necessarily HIV. Both men and women felt that sex was important to maintain the relationship. (Study 1) We received 245 messages with 42 themes. Expert review and cognitive interviews with more patients resulted in 42 messages with a clear division in terms of needs and expectations between the initial wound-healing recovery phase (weeks 1–3) and the adjustment phase (weeks 4–6). Participants were more positive and salutogenic than public health experts were. (Study 2) The randomised controlled trial found a slightly larger positive effect in the Intervention Group (28.0%) than in the Control Group (32.3%)) bot not significant (p=0.071). (Study 3) Participants gave the platform an overall usability score of 62.80 (SD 13.41). Most of them were positive about the messages. (Study 4)

Conclusions: VMMC counselling needs to take into account the real-life factors of the circumcised men. Due to systematic, social and cultural factors, there is a real risk that men in this population may initiate sex before complete healing has occurred. (Study 1) Consultation with potential mHealth recipients and using classic behavioural theories are vital to the success of a programme. (Study 2) Early resumption of sex after VMMC is common, warranting better counselling. M-Health technology is a potential tool but it should be complemented by other methods. (Study 3) The results suggest that the audio messaging system has good usability, user experience and user acceptance.

Keywords: m-Health; male circumcision; postoperative wound-healing period; health promotion; audio messaging; behaviour change

LIST OF SCIENTIFIC PAPERS

I. Y.Toefy, D. Skinner, and S. C. Thomsen, "'What do You Mean I've Got to Wait for Six Weeks?!' Understanding the Sexual Behaviour of Men and Their Female Partners after Voluntary Medical Male Circumcision in the Western Cape. *PLoS One* 2015; 108 7): e0133156.

II. Y. Toefy, D. Skinner, and S.C. Thomsen, "'Please Don't Send Us Spam!' A Participative, Theory-Based Methodology for Developing an m-Health Intervention. *JMIR m-Health uHealth* 2016; 4(3): e100.

III. Y. Toefy, D. Skinner, T.M. Esterhuizen, M. McCaul, M. Petzold, V. Diwan and S. Thomsen, Effectiveness of an audio-based cellular platform on increasing safe sexual behaviour during the healing period after male circumcision in Western Cape, South Africa (Unpublished, 2017).

IV. Y. Toefy, D. Skinner, and S.C Thomsen, A mixed-methods evaluation of an audio-based m-Health platform designed to reduce penetrative sex in recently circumcised men (Submitted to BMC Medical Informatics and Decision Making: Manuscript Number: MIDM-D-17-00096, 2017).

RELATED PAPERS

Thomsen Sarah C, Skinner D, **Toefy Y**, Esterhuizen T, McCaul M, Petzold M, Diwan V. Voice message-based m-Health intervention to reduce postoperative, penetrative sex in recipients of voluntary medical male circumcision in the Western Cape, South Africa: Protocol of a randomized controlled trial. *JMIR Research Protocols* 2016; 5(3):E155.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
DoH	Department of Health
GDP	Gross domestic product
HAPA	The Health Action Process Approach
HIV	Human Immunodeficiency Virus
ICT	Information and communication technology
LMIC	Low and middle-income countries
m-Health	Mobile health
PDA	Personal digital assistant
PEP	Post-exposure prophylaxis
RCT	Randomised controlled trial
SD	Standard deviation
SUS	System Usability Scale
TPD	The Theory of Planned Behaviour
VMMC	Voluntary medical male circumcision
WP	Western Cape

1 INTRODUCTION

1.1 GLOBAL HIV BURDEN

Since the beginning of the epidemic in the 1990s, the HIV virus has infected more than 70 million while around 35 million people have since died of the disease. As of 2015, between 34.0 and 39.8 million people worldwide were living with HIV. Of these 1.8 million were children younger than 15 years old.[1] An estimated 0.8% [0.7-0.9%] of adults aged 15–49 years worldwide are living with HIV, although the burden of the epidemic continues to vary considerably between countries and regions. An estimated 2.1 million individuals became newly-infected worldwide with HIV in 2015, including 150,000 children under the age of 15 years.[2] Most of these children live in sub-Saharan Africa and were infected by their HIV-positive mothers during pregnancy, childbirth or breastfeeding. As of June 2016, 18.2 million people living with HIV had access to antiretroviral therapy (ART) globally, up from 15.8 million in June 2015, 7.5 million in 2010, and less than one million in 2000.[1] Currently, the number of people infected with HIV globally who know their status, is estimated to be 60%. The remaining 40% do not have access to HIV testing services.[3]

Table 1: Newly infected HIV infections by region, 2015[1]

Region	Total No. (%) Living with HIV	Newly Infected	Adult Prevalence [%]
Global Total	36.7 million (100%)	2.1 million	0.8
Eastern and Southern Africa	19.0 million (52%)	960,000	7.1
Western and Central Africa	6.5 million (18%)	410,000	2.2
Asia and the Pacific	5.1 million (14%)	300,000	0.2
Western and Central Europe and North America	2.4 million (7%)	91,000	0.3
Latin America and the Caribbean	2.0 million (5%)	100,000	0.5
Eastern Europe and Central Asia	1.5 million (4%)	190,000	0.9
Middle East and North Africa	230,000 (<1%)	21,000	0.1

Table 1 clearly shows that the majority of the HIV burden remains in Sub-Saharan Africa, especially in Eastern and Southern Africa followed by Eastern Europe and Central Asia.

1.2 SUB-SAHARAN AFRICA

The Eastern and Southern region of sub-Saharan Africa remains most severely affected, with 19 million [17.7 million–20.5 million] people living with HIV in that region. Women account for more than half the total number of people living with the disease. Although new infections declined by 14% between 2010 and 2015, there were an estimated 960 000 [830 000–1.1 million] new HIV infections in the region. This number accounts for 46% of the new HIV infections globally.[2] The same level of decline holds true for AIDS-related mortality

which fell by 38% to 470 000 [390 000–560 000] over the same five-year period in the Eastern and Southern African countries.

1.3 THE HIV EPIDEMIC IN SOUTH AFRICA

1.3.1 Epidemiological context

Globally, South Africa has the largest HIV epidemic with an estimated seven million [6 700 000 - 7 400 000] people living with HIV in 2015. There were 380,000 new in 2015 while 180,000 South Africans died from AIDS-related illnesses in the same year.[4] Although South Africa's national HIV prevalence is 19.1% among adults (aged 15-49), the rate differs significantly between provinces. For example, the province of Kwazulu-Natal has an HIV prevalence rate of almost 40%, as compared to the lowest prevalence rate of 18% in Northern Cape and Western Cape.[5] There are several key populations at risk of HIV infection in South Africa for a variety of reasons. Among them are women, sex workers, children and orphans, men who have sex with men (MSM) and people who inject drugs (PWID).[3] Transmission of HIV in South Africa, however, remains almost exclusively through heterosexual sex.[3] The high prevalence rates means that effective use of proven interventions is essential.

1.4 THE HEALTHCARE SYSTEMS IN SOUTH AFRICA

There are two parallel health systems in South Africa, a private healthcare system that is well equipped and staffed, catering for the wealthiest twenty percent of the population and a public health system that is chronically underfunded and shortstaffed, that serves the vast majority of the South African population.[6] In 2005, South Africa spent 8.7% of its GDP on healthcare, which equated to US$437 per capita. Almost 79% of doctors work in the private sector.[7]

The vacancy rate for doctors working in the public sector stood at 56% and for nurses 46% in 2013.[8] The Department of Health stated that only 3% of newly qualified doctors take up residency in rural areas despite the fact that half of South Africa's population lives in these areas.[9]

Table 2: Public sector people-to-doctor and people-to-nurse ratio by province, 2015[9]

Province	People-to-doctor ratio	People-to-nurse ratio
Eastern Cape	4 280 to 1	673 to 1
Free State	5 228 to 1	1 198 to 1
Gauteng	4 024 to 1	1 042 to 1
KwaZulu Natal	3 195 to 1	665 to 1

Limpopo	4 478 to 1	612 to 1
Mpumalanga	5 124 to 1	825 to 1
North West	5 500 to 1	855 to 1
Northern Cape	2 738 to 1	869 to 1
Western Cape	3 967 to 1	1180 to 1
South Africa	**4 024 to 1**	**807 to 1**

Table 2 shows the high ratios of doctors to patients, especially in provinces that have a high rural sector such as Free State, Mpumalanga and North-West. However, even in the Western Cape there are about 4,000 persons for every doctor and almost 1,200 for every nurse in the public sector.

The high vacancy rates of health care personnel in the public health system in South Africa have implications for the quality of care that can be provided.

1.4.1 The South African response to the HIV/AIDS epidemic

In response to the high HIV prevalence rates in South Africa, and following many years of AIDS denialism within the National Government that drove public health policy from 1999 to 2008,[10] a program to distribute anti-retroviral therapy treatment nation-wide was formed by the government. In late 2003 the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa was finally approved, which was soon accompanied by a National Strategic Plan for 2007–2011.[11] The next two iterations 2012-2016 and 2017-2022 have expanded on these goals.[5] The distribution of anti-retroviral therapy has been successfully distributed through the primary health care sector that is housed in the public sector.[11]

1.5 HIV PREVENTION STRATEGIES IN SOUTH AFRICA

The fight against the spread of HIV infection in South Africa is encapsulated in the South African National AIDS Council's (SANAC) five goals strategy. These goals are a combination of behavioural, biomedical, social and structural prevention approaches combined with sustained quality treatment and care, as well as wellness programmes. They are also geared to look at the social and structural drivers that drive our current epidemics across all sectors, how to influence the impact of these epidemics, and examine the management of the way we care for people affected by the disease.

1.5.1 Voluntary medical male circumcision (VMMC)

Voluntary medical male circumcision (VMMC) became an important strategy in the fight against HIV infection when research showed the reduced risk of male acquisition of HIV by as much as 60 %.[10]–[13] WHO and UNAIDS issued a statement in 2007 that VMMC was to be recognised as an efficacious intervention for HIV prevention. They also recommended that VMMC should be promoted as an additional tool in the prevention of HIV in men. [14] A large proportion of sub-Saharan countries with high HIV prevalence were targeted for VMMC roll-out.[15] By the middle of 2014, over 5.8 million VMMCs had been carried out in the thirteen countries, over half of which occurred in 2013.[16]

There are some serious challenges that face male circumcision as a prevention strategy. The proclaimed protective factor of this medical procedure against HIV transmission [10]–[12] is mistakenly viewed by some as a fully protective measure and there are concerns that men who have been circumcised may be more inclined to partake in risky behaviours such as multiple sex partners and not using condoms. VMMC is also focussed on protecting men at the exclusion of women[17] and it focuses entirely on a biomedical method without looking at prevention strategies.[18]

In South Africa, a large proportion of the circumcision-seeking population does so as dictated to them by religious decrees and tradition, and the procedure is most often carried out in traditional ceremonies without clinical staff, although this is changing somewhat.[19] For example, the Xhosa community, which constitutes the vast majority of the Black population in the Western Cape, incorporates male circumcision as part of the ritual transition into manhood.[22] The challenges associated with circumcisions performed in these groups are that the circumcision procedure often does not remove the foreskin completely and therefore is not often as protective and because of the non-surgical environment in which these operation take place, surgical infections are a common occurrence.[20][21]

The South African government had committed to rolling out VMMC as a vital strategy in its fight against HIV infection.[4] The goal was to reach over 4 million adult men by 2015. At the end of 2013, however, the VMMC programme had only performed approximately 1.3 million male circumcisions since it started in 2010, which was only 31% of the 4.3 million target by 2015/2016.[23] This remains a focus for activity and emphasis will be placed on growing the rate of circumcisions, including the use of civil society partners for carrying out the procedure.[24]

Circumcision is provided as part of a comprehensive service at district hospitals, and, HIV testing, counselling and HIV education are recommended before the procedure.[14] This requires higher levels of resources and will be difficult to maintain.[25] Some provinces have thus out-sourced the service to non-governmental organizations (NGOs) who provide VMMC either in mobile camps or stationary clinics.

1.6 VMMC COUNSELLING ADHERENCE

1.6.1 Early resumption of sexual intercourse after VMMC

The World Health organization established clinical guidelines for the VMMC recovery period. Among the various wound management procedures, they recommend a six-week recovery period with no penetrative sex after the VMMC procedure to stop the transmission of STIs, including HIV.[12] A risk of early resumption of sex was identified and was associated with negative events and very low sexual satisfaction.[13] This risk was amplified in an environment without proper counselling, education and follow-up.[14] This seems to be particularly an issue for married men. In the Uganda trial, for example, despite intensive counselling, about 11% of study participants reported having engaged in one or more penetrative sexual encounters before certified wound healing.[15] Despite intensive pre- and post VMMC counselling within the trial, the group that were more at risk was the married group. This indicated a prevalent socio-cultural desire for quick restart of sex within a well-established relationship.[16] In a pragmatic observational study in Nyanza, Kenya, it was reported that 30.7% of the study subjects did not wait for the required six-week period to resume penetrative sex but it usually starts within 3-4 weeks after the circumcision procedure.[16] Likewise, it was also found that marriage and co-habiting was the strongest predictor of having early sex. The study reported 65.7% of married men resumed sex before the end of the wound-healing period. A recent study , also from Zambia also found that 24% of circumcised men resumed sex early, 46% of whom did so in the first three weeks.[17]

Health education messaging has to take cultural norms and the expectations surrounding sexuality into consideration when developing communication strategies. Qualitative research from Nyanza, Kenya, as well as other sites in the Sub-Saharan region indicates that the main complaint was that the post-operative abstinence period is spontaneously cited by uncircumcised men as a barrier to obtaining VMMC and that the six-week period was considered too long to abstain.[17] The younger men worried more about relationship that their female partners would seek sex elsewhere because they could not have some. The older men were also worried that it would not be possible to sleep in the same bed as their wives and abstain. Studies in Southern Africa around traditional circumcision also talk about the cultural phenomenon of “sharpened pencils” where the perception exist that circumcised penises heighten sexual pleasure, and therefore acts as an incentive for men eager to engage in sex as soon as they are able to.[18]

1.6.2 Pre- and post-operative counselling and education

The need for proper counselling and education during the wound-healing period stems around the need to adopt wound-safety behaviour. In the Rakai study, it a higher infection rate among female HIV- partners of HIV+ VMMC recipients was reported.[15] This makes it imperative that all effort must be made to mitigate this risk during this period.[15] Mehta (2009), in a pooled analysis of three efficacy trials, acknowledged that the intensive counselling done with the participants received is not reflective of the standard of care offered

to VMMC recipients in these countries. The study found no increased risk for HIV acquisition for men who reported an early resumption of penetrative sex compared to men who did not, they.[19] Herman-Roloff, Bailey, and Agot (2012) looked prospectively at the time it took to engage in sexual activity. They found participants who engaged in early sexual activity were more likely to 25 years and older, working, and married, and HIV positive (Pearson's $\chi 2 = 5.9$, $p < 0.05$).[16] A second study conducted by Rogers et al (2013) also found that the risk factors of being married, older 25 years, being HIV-positive, consuming alcohol, and being multi-partnered are associated with early resumption of sex among men in Kisumu (n = 323).[20] Clearly, this programmatic gap needs to be filled by using more innovative methods of post-operative counselling for recipients of VMMC. One possibility is m-Health.

1.7 M-HEALTH

1.7.1 Mobile Health (m-Health) as a self-care strategy

With more pressure on the public health sector in terms of budgets and staff shortages, as opposed programme developers have started to look at self-care programmes as a means to address some service delivery challenges.[21]. Due these challenges, the idea of mobile phone technology to assist and deliver health care remains outside traditional healthcare channels. [22]

Figure 1[23] provides an overview of the current and potential uses of m-health. Disease management of diabetes, asthma, hypertension, obesity and HIV treatment are ideal candidates for m-Health programmes, in the form of mobile phone text messaging [24]–[28]. Mobile phone text messaging also assist in socially bad situations such as reducing alcohol consumption, stopping smoking, obesity management, and lastly, and not the least, , sexually transmitted infection, prevention and testing.[24], [26]–[28] Mobile devices are also used for data collection purposes, both in in healthcare and biomedical research [23], [29], [30]. Medical education, clinical practice and support services are all good candidates.[31]–[33] Traditionally, the development of M-health interventions has always been in concentrated in the high income countries, but as global mobile phone usage patterns have changed towards a concentration in low income countries, a string of mobile technologies have emerged from this region. [28], [34]–[36] Despite the recent upsurge of mobile use in low income countries, the mobile and wireless networks have not been developed at a similar rate.[37][38] There is still a huge potential for M-health interventions to have positive effects on health outcomes.[35]

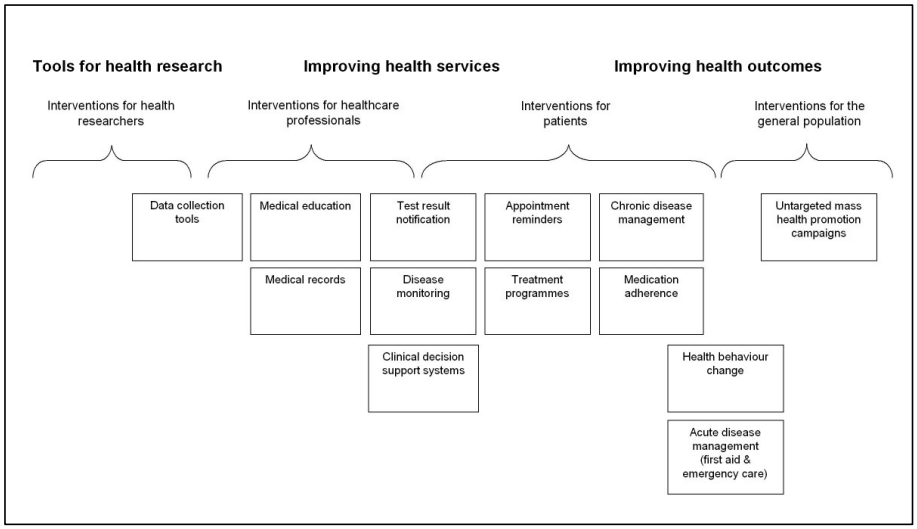

Figure 1m-Health uses in the field (A. Chib, M. H. van Velthoven, and J. Car, 2014)

There is near universal ownership of cell phones in South Africa: 97% of household have a mobile phone, with the urban centres having a higher degree of saturation. Particularly within the urban setting there is little difference by income level in terms of access to phones.[32] The near universal spread of cell phones in South Africa, mobile phone technology has been found to be viable for health services and feasible for HIV and AIDS-related prevention and services in South Africa,[33][34] and is now used in several health-related text-reminder projects in South Africa. [35][39].

The efficacy of m-health interventions in the clinical environment is well-studied[22][40] but there not much on the effectiveness of m-Health interventions on behaviour change. Chib (2014) suggests that the existing feasibility studies on the first five columns of the m-Health categories in Figure 1, only focus on how feasible, implementable, adoptive and acceptable of the technology the user is., as opposed to their effectiveness on health outcomes.[23]

The majority of m-Health interventions with a messaging component have only used text messages (SMS). Text message reminders to improve medication adherence for people with chronic illnesses have been evaluated via randomised trials in Low to medium income countries (LMIC)[38], [41]–[43]. Lester et. al. (2010) found in a Kenyan randomized controlled study that patients who received SMS support had significantly improved ART adherence and rates of viral suppression compared with the control individuals (relative risk [RR] for non-adherence 0·81, 95% CI 0·69–0·94; p=0·006)[44][45]. In another Kenyan RCT, Pop-Eleches (2011) found similar success, where 53% of the participants receiving weekly SMS reminders achieved adherence of at least 90% during the 48 weeks of the study, compared with 40% of participants in the control group (P=0.03).[45] Two recent systematic reviews found modest and suggestive evidence for the benefits of text-based m-Health technology[46]

1.7.2 Voice messaging m-Health interventions

Voice message m-Health systems for behaviour change are relatively under-studied although there are a few published studies on its effectiveness. Voice messaging as an intervention has been used effectively in the fields of nutrition and weight-loss and smoking cessation programmes. In Nigeria, a behaviour intervention using a combination of approaches, including voice messaging, were used to change or enforce breastfeeding patterns.[47] A study trying to improve the adherence to diabetes treatment used voice messages quite successfully.[48] On the other hand, De Costa and her team (2010) found that voice message reminders had no effect on adherence in antiretroviral treatment in South India.[49][50].

Only one RCT of a telephone-delivered intervention - to increase uptake of post-exposure prophylaxis (PEP) for rape victims A Cochrane review from 2013 found - for preventing HIV infection in HIV-negative persons. A counsellor followed participants up telephonically throughout the 28 days when they had to take PEP treatment. The aims of the intervention were to encourage the participants to stay on treatment, to seek significant-other support, to attend counselling, to read and understand the information pamphlet, to utilise the medication diary and to return to the clinic for the follow-up. The estimated effect of telephone counselling was 6.5% (95% CI: 4.6 to 17.6%) and not statistically significant (P=0.13).[51]

1.7.3 The need for theoretical frameworks in the development of m-health interventions

Health behaviours are strongly affected by experiences, perceptions, and capacities of individuals, which are informed by social environments.[52] There are theories of behaviour change that are well validated and well tested on evidence-based interventions. Research show us that these grounded interventions are few and far apart.[53] Tomlinson et al (2013) contends that down-stream interventions, which are programmes that was only designed based on information transfer only will fail at their implementation phase.[54]

Effectiveness studies of m-Health interventions that do not consider the nature of behaviour change may find false negative results. That is, if the intervention shows a negative result, and the designers are only focused on the technology, they may decide that the intervention is not effective because of design reasons such as usability of the platform and thus may reject it. However, the intervention may have been ineffective because it did not take into account how individuals make decisions about their health. Therefore, a plausible theory of behaviour-change with the m-Health interventions should be guided by more than one technique depending on the targeted behaviour. The dynamic nature of the changing technology arena demands that m-Health researchers must be more innovative in their methodology and use appropriate methods throughout the development cycle. Novel research methods allow researchers to capitalise on technological advances and more rapidly disseminate research findings.

The theory of Planned Behaviour and the Health Action Process Approach (HAPA) are two behaviour change theories that are often used in the public health arena.[55]–[59] The former

being a cognitive theory that, in general, predicts that a set of beliefs will predict a desired behaviour outcome, while the HAPA is a stage-step theory that ‘moves’ the individual one step to the other towards the achievement of the desired behaviour.[58][60]

The Theory of Planned Behaviour

The Theory of Planned Behaviour (TPB) is a theory that provides the impetus of many behaviour change interventions that exist today.[61] In 1991, Icek Ajzen proposed it as a process to improve the predictive power of the Theory of Reasoned Action. This was done by including perceived behavioural control to the exiting TPB’s model. The Theory of Reasoned Action was formulated eleven years earlier by Ajzen and Fishbein [62] and this behavioural theory suggests that human behaviour is guided by three kinds of beliefs and norms: behavioural, normative and control. In combination, "attitude toward the behaviour," "subjective norm," and "perceived behavioural control" lead to the formation of a "behavioural intention". In the realm of messaging development, the first norm, behavioural attitude, convinces the participants of the usefulness, worth, and advantages of the proposed behaviour. Thus, the Theory of Planned Behaviour proposes that when individuals are convinced of the worth of the behaviour are more likely to adopt it.This theory is interesting for the development of the *content* of behaviour change messages.[63]

In an Australian study on improving hand hygiene among health care workers, White et.al (2015) used a planned behaviour framework to explore in a systematic way, the underlying beliefs of nurses’ hand hygiene decisions according to the five critical moments as set out by the WHO hygiene framework. The study found a combination of the three elements of planned behaviour, namely, behavioural, normative and control beliefs influenced the level of commitment of the nurses to improve their own hand hygiene practices. The framework focused on the three elements of the model. It looked at *individual strategies* to counter the distraction from other duties the nurse must fulfil; it looked at *peer-based initiatives* within the workplace that were designed to foster a sense of shared responsibility on the issue of hygiene, and finally, it proposed *management-driven solutions* to tackle staffing and resource issues. This theory is thus appropriate for use in designing messages for concrete behaviour change.[64]

The Health Action Process Approach (HAPA)

The Health Action Process Approach (HAPA) is an open behavioural framework that consists of a variety of motivational and volitional constructs.[65] These constructs are proposed to describe and calculate individual changes in health behaviours in domains such as smoking or drinking cessation, dental hygiene, condom use, breast self-examination, dietary behaviours[66] and avoiding drink driving.[67] This approach is based on the assumption that the adoption, initiation, and maintenance of these behaviours should be conceived of as a structured process including a motivation phase and a volition phase. The former describes the intention formation while the latter refers to planning, and action (initiative, maintenance, recovery). Self-efficacy at the different stages of health behaviour

change is also central to the HAPA model.[68] We could not find the HAPA model used in any HIV prevention messaging intervention in the literature.

The Action Research Approach

In addition to the two behaviour change theories, the study also used the Action Research approach. This approach was developed by Jacobs and Graham (2016), who linked iterative health behaviour intervention development and research methodologies and concluded that the requirements and solutions of these methodologies were evolved through collaboration between the developers and their intended target audiences. The method promotes adaptive planning, evolutionary development and delivery, and encourages rapid and flexible response to change and allows a project to adapt to changes quickly.[69] Several m-Health intervention development programmes have previously concluded that partnering with the target population in the message development is critical to ensure that a salient final product and feasible protocol are created.[70]–[72]

The Action Research approach was applied in two levelsin our message development. First, recent recipients of VMMC and female partners of VMMC recipients were asked to come up with messages that they thought would be helpful during the recovery period through focus group discussions. Then, the participants in cognitive interviews verified these messages through explanation and ranking.

The other level in which Action Research approach was used was in the progression and rate of the messages. The ordering of the messages was designed to assist with the resolution of a particular issue or crisis as they occurred during the six-week period as highlighted by the participants. The progression of issues in the six-week period also dictated the rate the messages were delivered to the participants.

1.8 PROBLEM STATEMENT

Several studies had shown that men recovering from VMMC, before the penile wound is healed, engage in penetrative sex during their recovery period. This leads to an increased risk of transmission of STIs, including HIV, in the immediate post-operative period after receiving VMMC. Recommendations have been made for developing and evaluating optimal counselling strategies among men seeking VMMC and to assess the effectiveness of behaviour change communication strategies [21]. However, there is also recognition that a lack of human resources presents a barrier to the provision of such intensivee services, particularly if repeated messaging is to occur. M-Health has been proposed as a method of reducing burdens on the health system in resource-poor settings. However, there is a lack of theory-based m-Health intervention development. Additionally, there is very little evidence in general of the effectiveness of m-Health interventions for behaviour change.

1.9 AIM

The overall aim of the study was to develop and evaluate – through a randomized, controlled trial – a voice message system to increase the adoption of safe sexual behaviour during the post-operative period for medically circumcised men in Western Cape Province, South Africa.

1.9.1 Specific aims of the studies

- To develop an understanding of the study population's sexual behaviour and perceptions during the six-week post-operative period following VMMC in the Western Cape Province. (Study I)
- To develop comprehensible and acceptable messages about safe sexual behaviour during the healing period for recipients of male circumcision in the Western Cape Province using a theory-based, participatory approach. (Study II)
- To assess the effectiveness of a voice message system on increasing safe sexual behaviour during the healing period for recipients of male circumcision in the Western Cape Province. (Study III)
- To assess the usability of an audio-based cellular platform to improve counselling about safe sexual behaviour during the healing period for recipients of male circumcision in the Western Cape Province. (Study IV)

2 METHODS

2.1 STUDY SETTING

2.1.1 The Western Cape and the City of Cape Town municipality demographic and socio-economic indicators

The research for this thesis was conducted in the City of Cape Town municipality of the Western Cape Province of South Africa. Below follows a brief introduction of the demographic and socio-economic background of the province and its sub-structures.

Figure 2: The Provinces of South Africa

The Western Cape Province is one of the nine provinces of South Africa. It is situated in the south-western part of the country. It is the fourth largest province in South Africa, at 129,449 square kilometres. (Figure 2) It also has the fourth largest population of South Africa (11.3%), with 6.2 million inhabitants living in 1,634,000 households.[73] The population density of the Western Cape is 45 inhabitants per square kilometre and the household density is 12.6 persons per square kilometre.

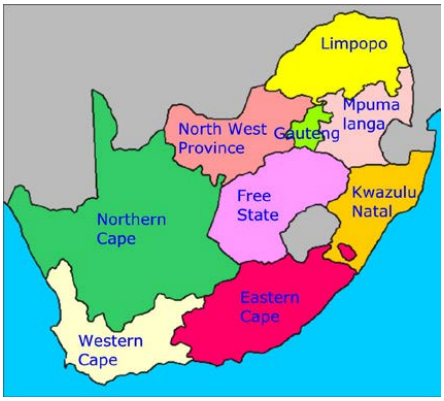

Figure 3: The municipalities of the Western Cape

The Western Cape's total gross domestic product (GDP) for 2016 was R424bn (US$29.3bn), making the province the joint second largest contributor to the country's total GDP (14%). It also has one of the fastest growing economies in the country, 2.7% in 2016.[74] The average annual household income of the Western Cape is R57,300 (US$4,275), the second-highest in the country after Gauteng and almost double the national average of R29,400 ($2,192).[75] According to Figure 4 about 20% of the population of the province live on under R10,000 (US$740.88) per year, which is well under the established poverty line in South Africa.

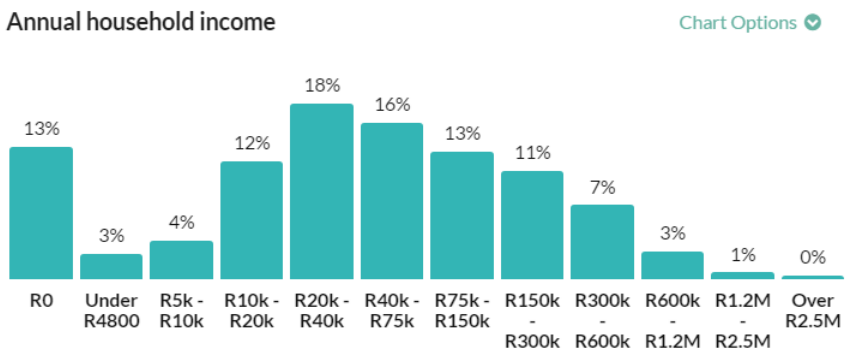

Figure 4: Annual household income Western Cape

The Western Cape and Gauteng are the only two provinces in South Africa to have a positive migration trend. In other words, more people migrate into these two provinces rather than migrating from them to other places.[76] There is a high level of economic migration into the Western Cape , as roughly 16% (894,289 people) of the Western Cape's population in 2011 were born in the Eastern Cape, 3% (167,524) in Gauteng and 1% (61,945) in KwaZulu-Natal. People born outside of South Africa amounted to 4% of the province's population or 260,952 people.[74] As of September 2012, 69% of the population aged 15–64 are economically active, and of these 25% are unemployed.[75] This is slightly lower than the national

unemployment rate of 26.5%.[75] The three economic sectors that hold most our labour force are finance, insurance, property and business services; Manufacturing; and wholesale and retail trade, catering and accommodation.

At 45.4%, the largest racial group in the City of Cape Town Municipality is Coloured[1], followed by White (42.7%). The African grouping (8.6%) and Indian/Asian groups (1.4%) are in the minority (Table 3). We find the same racial pattern in the greater Western Cape with the exception of the White and the African groupings swopping rankings in the broader province.[77] This is evidence of a high concentration of African communities in the rural and smaller town in the Western Cape.

Table 3: Racial breakdown in the City of Cape Town and the Western Cape overall

Percentage share by race group	City of Cape Town	Western Cape
Coloured	45.4%	42.4%
White	42.7%	15.7%
African	8.6%	38.6%
Indian/Asian	1.4%	1.4%
Other	1.9%	1.9%

The studies were conducted in the catchment areas of twelve public health clinics (Appendix 1) with MMC clinics in City of Cape Town municipality (Figure 5). Studies 1 and 2 used the same population drawn from the Heidevelt Public Health Clinic and Mitchells Plain Hospital in the Central Substructure. Study 3 selected its population from all twelve VMMC clinics in the Southern, Northern and Central sub-structures while Study 4 selected its participants from the intervention arm of the RCT in Study 3.

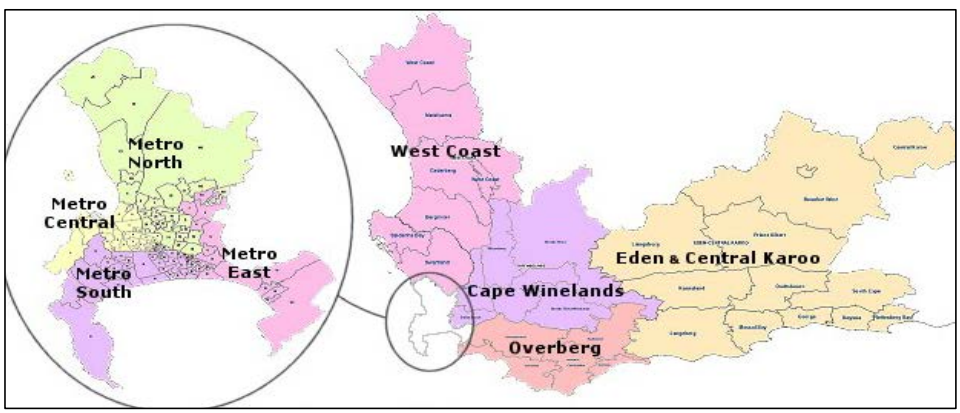

Figure 5: Western Cape municipal health regions and the City of Cape Town health sub-structures

1 The term Coloured refers to an official South African race group that is predominantly mixed ancestry that is used in research and census data.[6]

The province is divided into six municipal districts (Figure 5) with about two-thirds of inhabitants living in the municipal district of the City of Cape Town, also known as the Cape Metro. The Cape Town municipality's urban geography is influenced by the contours of Table Mountain, its surrounding peaks, the coastline, the Durbanville Hills to the north, and the expansive lowland region known as the Cape Flats.

The suburbs on the coastline and on the slopes of Table Mountain and surrounding mountains contain a large number of wealthy communities with an income of R2.5-million a year or more.[76] These communities are almost exclusively White. The Cape Flats, on the other hand, are a combination of low-cost housing and slum areas.[77] There are also wide belts of semi-rural farming areas on the flats. According to the 2013 tax statistics, the average taxable income of the City of Cape Town municipality is R241,704.[76]

The majority of the townships[2] in the Cape Town area are densely populated (population density 9,600 per km^2[73]) with a low socio-economic base and an unemployment rate of 20.9%.[75] The housing is typically one to two-bedroom" maisonette" housing with an average population density of 9,600 per km2 and an average house density of 4.57. The community is predominantly Christian but there is a large Muslim population (10–15%) in the townships.[78]

Between 2001 and 2010 the city's Gini coefficient, a measure of economic inequality, improved by dropping from 0.59 in 2007 to 0.57 in 2010 only to increase to 0.67 by 2011/12. A Gini coefficient of 0.67 points to a very unequal society as the international alert line for high inequality is only 0.4.

2.1.2 HIV and risk factors in City of Cape Town municipality

The South African HIV prevalence rate varies widely according to race: from 31.7% among the Black group to 2.2% among the White group, with the Coloured's prevalence rate at 7.5% according to national antenatal data.[5] The Coloured community has a rising adult HIV prevalence trend as it was 7.0% in 2010, 7.6% in 2011 and 7.5% in 2012.[8][3] The heightened HIV risk in this population group lies at least partly in a high illicit drug and alcohol use in the community, which is statistically associated with risky sexual behaviour.[8], [9] It has a high level of gangsterism in the townships that serves to weaken the fabric and rules of the community.[79] The Coloured community has historically had a lower level of HIV infection, and do not see themselves as vulnerable. There is a strong undercurrent of racism and stigma in the community as HIV is seen as a 'Black' disease or a disease that belongs to other distant communities.[80][81] This has implications for the kind of HIV prevention messaging that is effective in this community.

[2] (Term used in South Africa) A suburb or city of predominantly non-White occupancy, formerly officially designated for black occupation by apartheid legislation.
[3] There are no updated HIV prevalence data broken down by racial groups beyond 2013.

Healthcare in the City of Cape Town

In the municipal region of the City of Cape Town, there are 164 healthcare facilities operational in the city, some operated by the Department of Health, while others are operated by the City of Cape Town. Public secondary care services are provided by nine district hospitals and two regional hospitals.[82]

Table 3: Healthcare facilities in the City of Cape Town municipality, 2014

Primary Healthcare Facilities 2013	**Number**
Community Health Centres	9
Community Day Centres	38
Clinics	84
Satellite clinics	18
Mobile clinics	4
District hospitals	9
Regional hospitals	2

HIV prevention and VMMC service delivery in the City of Cape Town municipality

In 2014, the Provincial Department of Health released the Provincial Strategic Plan on HIV, STI and TB, in which it spelled out its broad 20-year plan through four objectives:[83]

- Concentrate on the social and structural approaches to HIV and TB prevention, care and impact
- Utilise all resources to prevent new HIV and TB infections
- Sustain health and wellness
- Protect human rights and the promotion of access to justice

VMMC is a critical area of the Department of Health national strategic plan and is available at all the major clinics in each sub-structure. There are one mobile VMMC team per sub-structure, and the patients are recruited by themselves, the medical staff at the clinic or an DoH appointed non-profit organisation who access the community structures and networks to recruit VMMC patients. The other areas include the promotion of HIV Testing through the HIV counselling and testing campaigns, the promotion of both male and female condoms, facilitate behaviour change to reduce transmission risk factors, promote active TB case finding and promoting adherence to treatment until completion and finally, to promote social mobilisation to encourage the above-mentioned strategic areas.[83][5]

By March 2014, antiretroviral treatment (ART) was provided to 116,421 patients from 73 treatment sites in the City region and TB Treatment was provided to 26 305 patients in 208 TB clinics/ treatment sites in the City of Cape Town municipality.[82]

In the Western Cape, a total of 15 498 VMMC procedures were performed in 2014/15 and this figure decreased in 2015/16 to 13 310. This was 9 589 short of the annual target of 22 899 the department set itself.[84] Figure 5 below shows that the downward trend also exists at a national level as the amount of VMMC procedures done nationally in the public

health sector since 2010 falls a long way short of the target set by the Department of Health.[85]

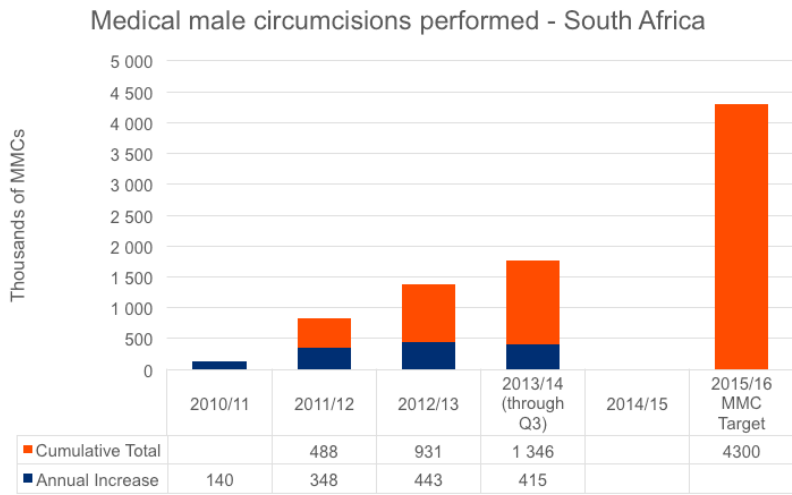

Figure 5: MMCs performed in the public sector from April 2010 to December 2013 vs.2015/2016 targets

2.2 UNDERSTANDING THE CONTEXT (REFLEXIVITY)

As a researcher with more than 14 years' of experience in the facilitation of in-depth interviews, focus groups and quantitative survey tools, I am quite comfortable with myself as an interviewer. However, looking back at the study and formally reflecting on my own skills, I realised that I still had many issues I needed to resolve and keep track of. In addition to being trained as a researcher, I am also a Muslim who was circumcised as an infant, and I have formal training as an Imam and a family counsellor within a pastoral environment.

I am including three extracts from my fieldwork journal I kept during the qualitative phase of the study to illustrate these issues.

My Interpretive Crisis

> *I am a circumcised man, and so far all my participants in the project are men who have been circumcised or their partners who live with these men. I realised early that I am not a neutral participant in the research project. I have issues, concerns and opinions about male circumcision. I have desires for the project and what it will achieve or discover that are bound up with my views on assessment of the programme and what it should be or achieve, what is desirable and undesirable. I realised that I, in terms of qualitative work, was not an objective data-gathering tool. If I were to take the view of the traditional methodology texts on interviewing, in the light of the above points, I should be*

particularly concerned about my role in the research process as the main instrument of data collection. (Personal research journal, 10/4/2015)

"Faking" it?

I felt strange acting in the role of interviewer... because of my affinity with the participants. I didn't put this out in the open, and wonder if I should have? I felt as though it was a bit fake and not like the equal conversation that it could be if we just sat around and discussed circumcision issues and if I felt free to say more. I stuck to the guidelines according to the discussion schedule. I did probe, and I did give some personal examples and opinions. I restated and clarified, which, at the time I worried about whether I was "contaminating" the data. Also, having my own opinion and experiences and wanting to join in the discussion was an issue, so I did resist this and felt a little 'fake'. (Personal research journal, 12/5/2015)

My crisis stemmed from the fact that I did not find myself in a "neutral" or "objective" space when I facilitated the focus groups. Instead of managing the group discussions objectively and looking for talking points and segues into the next discussion point, I instinctively found myself involved in the discussion. I had to remove myself from the conversation in order to facilitate in a coherent and somewhat neutral manner. I am naturally very opinionated when discussing topics that I feel passionate about. I was very worried that as a facilitator with much power in the group, I was going to influence the group dynamic and therefore skew the data. So when a contentious point was brought up that I had twenty responses to, I physically had to constrain myself and say: "Oh that's interesting, what do you guys think about it?" My feelings of "fakeness" stemmed from those exchanges.

My "Cognitive Baggage"

The problem is the grey areas in deciding what messages will work and at what frequency they should be transmitted. Is the main thing the ability for the man to understand the context of the messages or the extent to which the messages will influence his decision-making processes? And how does one assess those things? My idea of understanding and behaviour impact may be different from another person... We have clear performance criteria set for the project, but there are still grey areas, and many of the performance criteria such as partner communication and pain reporting, are subjective and open to interpretation. I have struggled with the conflicts in my role as assessor, supporter, communicator, listener, for both the participants and managing the project. I think I am too soft and I worry about being fair all round. (Personal research journal, 5/4/2015)

In my experience over the past decade in assessing behavioural interventions, I have always been cautious about the drivers of behaviour change, especially running a project within a community setting with much "noise". I struggle with tying down the causal factor of the change, if there was any. Is it the content of the messages and what we intended it to be, or could it be something completely out of our realm of control? Perhaps it's the nagging of the

messages, or the motivation might be merely the fact that the person is in a research programme.

These three dilemmas forced me to ensure that I kept a tight and objective reign on my own issues while I was analysing the data. The manner I used to safeguard the analysis was to have my supervisors review my conclusions and results I obtained from the data and whether my interpretations seem to be representative of their knowledge and beliefs. I also verified the results with quantitative data we obtained from the participants. During the data collection of Study one, I had the opportunity to triangulate the responses of the VMMC patients and how they viewed the role of sex in their relationships with their partners independently. I also tried to check for alternate explanations to the conclusions I drew from the data by using theoretical frameworks and in that way strengthened my interpretation. An instance of this, was when I looked at the transcripts of the focus groups in Study two that looked at the way VMMC patients managed pain and discomfort in the first week following the operation, I found much clarity in the way they expressed themselves when I viewed it through the multi-staged behavioural model such as the Health Action Process Approach (HAPA).

2.3 THESIS OVERVIEW

Table 4: Thesis overview

Study	Domain	Research questions	Study design & population	Timeline	Outcomes and conclusions?
I	PRE-TRIAL: Understanding the sexual behaviour of men in VMMC post-op period	• Why do men in a predominantly Coloured community of South Africa, seek VMMC? • What were their experiences of the post-operative period in terms of penile recovery? • Why do men resume sex early after the VMMC procedure? • What sexual strategies do couples employ to negotiate the 6-week recovery period?	Focus group discussions 6 male groups (n=38) 3 female groups (n=14)	July – Aug 2014	• Reasons for VMMC: religious injunction, hygien, protection against STIs (not necessarily HIV). • Verylittle alternative non-penetrative sexual practices. • Pain and fear of any sexual arousal dominated first 3 weeks; sexual desire returned in last 3 weeks. • Sex seen as essential to maintain the relationship. • Counselling gaps in pre- and post-MC procedure.
II	PRE-TRIAL: Developing and testing a participative, theory-based m-health intervention	How can a mobile phone audio messaging intervention to task shift post-operative counselling on wound management and goal setting on safe sex be developed using a participative, theory-based methodology?	Content analysis, expert consultation, Cognitive interviews Same cohort as Study 1 + 12 recently circumcised men	Aug – Dec 2014	• Classic behavioural theories can and should be used to design modern m-Health interventions. • The target audience are the best source of messaging, ensuring that messages are culturally relevant to the recipient. • Patients prefer more salutogenic messages than experts.
III	RCT Cohort study to improve safer sexual behaviour in the VMMC post-op period	Can an m-Health intervention based on mobile audio messages decreases the prevalence of penetrative sex among recuperating circumcised men during their six-week wound-healing period in clinics in the Western Cape Province, South Africa?	Randomised Controlled Trial 1,188 men recruited from 12 clinics in Western Cape	Jan 2015 – Jun 2016 Data un-masking and analysis: Aug 2016	• A slightly larger positive effect in the Intervention Group than in the Control Group • Alcohol use and anxiety associated with early penetrative sex. • Participants in the control group were less likely to engage in non-penetrative sex. • The intervention may have more effect on individuals with high risk propensity than those who do not.

Study	Domain	Research questions	Study design & population	Timeline	Outcomes and conclusions?
IV	NESTED IN STUDY 3: Assessing the usability of an m-Health platform	How dide users rate the usability of the m-Health platform:?	Questions embedded in follow-up questionnaire. Focus group discussions Experimental arm of Study 3 (n=597) + 5 focus groups with 25 recent patients	Jan 2015 – July 2016	• Usability of the system ranked as 62.80 (SD 13.41). • Results from the focus groups suggest that most of users were positive about the messages.

2.4 STUDY METHODOLOGY

2.4.1 Study I

Study I was a retrospective study using focus group discussions with medically circumcised men attending the VMMC clinics in Heidevelt and Mitchells Plain in the Central Municipal Sub-Structure of the City of Cape Town municipality between February 2014 and July 2014. A contextualised interpretative analysis was used to develop a better understanding of how men and their partners feel about VMMC and sexual patterns around the wound recovery period. The interviews covered issues around the men's motivation to seek the VMMC procedure as adults such as how they experienced the medical procedure and what coping strategies they employed to manage the initial post-op period. The interview then explored how the men and their sexual partners managed a resurgent libido during the recovery period. The interview also investigated the cultural importance of maintaining a sexual relationship with a regular partner during the recovery period. During the interviews, we also collected information used in study 2.

The study included six focus groups with men and three with women (Appendix 5). The sampling was done in conjunction with the VMMC booking officers at the two participating clinics. Male participants were randomly drawn from the VMMC theatre records of the last six months. The records consist of monthly lists of names, ages and contact details of VMMC recipients over the past six months. The fieldworker contacted all men on the clinic lists starting from the earliest month to the latest. Three men declined to participate at the initial contact point, citing time-constraints, and five men who initially agreed to participate, did not arrive at the group sessions. No information is available on them and other than citing time constraints, no other reason for not coming were given.

At the end of each focus group, the facilitator asked the participants if they would be willing to share the names and contact details of their sexual partners over the six-week post-operative period. Of the 38 men who participated, 26 men gave details of their partners. Reasons for not giving the details of their partners ranged from not knowing where their ex-partners are to the stated conviction that their partners would not participate in focus groups. No men reported having a male partner. The researcher contacted these partners by phone?, which resulted in three focus groups with women (n=14) who were partners of men who had recently undergone VMMC. Seven women refused to participate (time constraints, personal reasons) and five women did not arrive at the sessions. No additional information is available

on those who did not participate. After obtaining informed consent, male patients and their partners were organized into gender-specific focus groups and interviewed between July and August 2014.

All of the participants had been residents in the community for most of their lives and were Coloured. The population of the clinic's catchment area is largely of the 'Coloured' race group and about 10-15% is Muslim. The study population reflected this demographic breakdown.

2.4.2 Study II

The purpose of this study was to develop a participative, theory-based, mobile phone audio messaging intervention attractive to recently circumcised men at voluntary medical male circumcision (VMMC) clinics in the Cape Town area in South Africa in order to task shift some post-operative counselling on wound management and goal setting on safe sex.

We developed an m-Health intervention using a staggered qualitative methodology: 1) focus group discussions with 52 recently circumcised men and their partners to develop initial voice messages they felt were relevant and appropriate; 2) thematic analysis and expert consultation to select final messages for pilot testing; and 3) cognitive interviews with 12 recent VMMC patients to judge message comprehension and rank them (Figure 6). The message content and phasing was guided by the Theory of Planned Behaviour and the Health Action Process Approach.

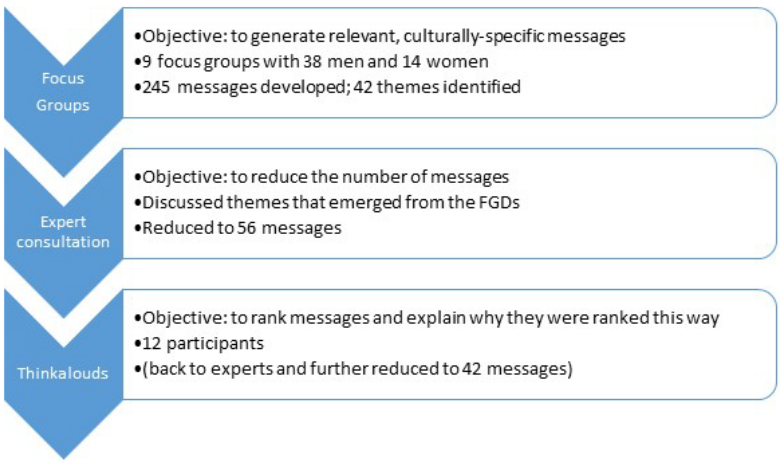

Figure 6: Steps to develop the content of the m-Health intervention

Study II used several participative, qualitative methods to develop the m-Health phone messaging system and their sequencing, placing emphasis on the user's needs and experiences. The first step was to use the focus group discussions with 52 recently circumcised men and their partners used in Study I to develop the initial messages they felt were relevant and appropriate. Before the discussions for Study I began, participants of these focus groups were asked to write down five messages they felt could have assisted them

during this period. Focus group participants were given pieces of paper and a pencil, and on their own, wrote down five messages, which they folded and placed in a bag that was circulated in the group. By asking the respondents to develop the theme list, we were drawing out the relevant issues to improve motivation and reduce blocks to volition, as well as identifying key behavioural, normative and control beliefs. Additionally, information on the general acceptability of mobile messaging, generation of appropriate and relevant messages to recipients of VMMC during their 6-week recovery period, and the acceptable frequency of mobile messages was collected.

The second step was the development of the final messages for pilot testing through thematic analysis and expert consultation with a Department of Health behaviour-change communication expert. As a first step, we looked at the raw list of messages generated by the focus group participants, then deleted incorrect, duplicate, and repetitive messages. We then grouped the remaining messages into themes and through inter-rater agreement, we decided on one or two messages representing each theme. At this stage, we adjusted several messages for technical correctness and added crucial but missing themes such as HIV prevention messaging. This occurred between July and October 2014.

The final step was to select 12 patients from the two participating VMMC clinics in Study I through the clinics' registrar offices. The two selection criteria were that they had to be 18 years old and above and they had to have completed the six-week wound recovery period in the previous month. They were invited to individual cognitive interviews between October and December 2014. The cognitive interview or "think aloud" method was designed to track the processing of information through verbalisations while performing a task as it is involved in decision-making. These verbalisations are the actual clues to researchers to how decisions are arrived at.[86]

Cognitive interviews were conducted in the following manner: each message was read out to the participants and then tested for comprehension, such as repeating the message in their own words. We then probed for the participants' perception of the aim of each message. Following each section, participants were asked to reflect on the time period in the 42-day period for which this group of messages was designed. They were then asked to rank the messages in the group for appropriateness and clarity. The messages were put in groups of 3-6 messages for ranking purposes. Following the ranking exercise, using a think-aloud method, participants were asked to reflect on message grouping and whether there were any messages missing that could have made a difference, whether there were any unnecessary and inappropriate messages and to reflect on the reasons why they ranked the group in a particular way. This refines the contributions from step 1 improving the messages in terms of both the Theory of Reasoned Action and the HAPA.

2.4.3 Study III

Study III enrolled patients who accessed twelve VMMC clinics in the South, Northern and Central sub-districts from January 2015 to April 2016 (Figure 7). Patients were eligible for

this study if they were circumcised at the clinic on the day of recruitment, consented to participating in the study, were 18 or older, possessed a mobile phone and were planning on being in the area for the six-week follow-up.

Study III utilised a two-armed, randomized, single-blind, controlled design (Pan African Clinical Trial Registry (PACTR201506001182385). Only the patients were aware of the intervention assignment; while the clinic and research staff assessing patients, as well as statisticians, and authors were blind to the allocation.

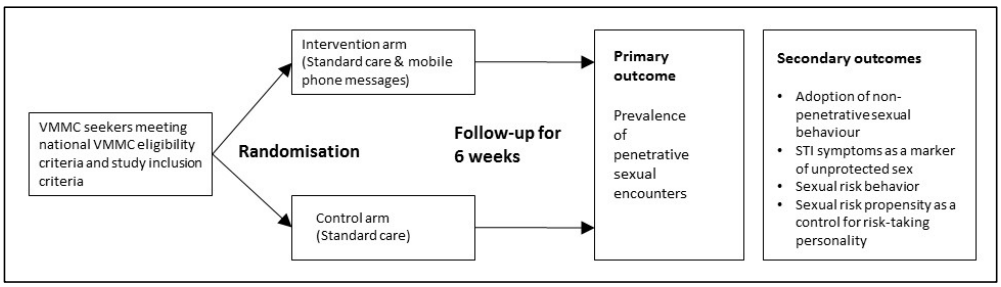

Figure 7: Trial design and outcome measures

Randomization: The study utilised a random allocation rule method to generate a randomization sequence. Through this simple randomising technique, we generated the random sequence (a 1:1 ratio in each group) for the entire trial using a computer-generated table of random numbers. The assignment sequences were placed in consecutively numbered opaque sealed envelopes and the study numbers were assigned consecutively to the participants as they entered the VMMC programme. Only the Office Manager had access to the sequencing master list ensuring adequate allocation concealment.

Standard of care: The standard of care offered by the provincial circumcision team consists of the counselling session during the VCT procedure and a brief post-surgery counselling session, where they are advised on how to care for the wound and requested to go to their local clinic after two, seven and 14 days following surgery. They are reminded not to engage in penetrative sex until the mandatory wound-healing period of six weeks has passed. No further contact, beyond the three wound caring sessions, is provided unless the patient experiences complications such as swelling or infection.

Intervention: The intervention group received the standard of care, plus the intervention programme that consists of 38 audio messages that were delivered over the 42 days following surgery. The content and phasing of the messages for the m-health intervention were developed collaboratively with former patients and health promotion experts at the Provincial Medical Office as described above.. The messages were then developed into short audio clips of 30-120 seconds each (in English and Afrikaans). Based on the formative research, messages are over the 42 days were divided into four periods:

Days 1-2: An intense two days of self-care messages (two per day). The theme of these messages revolves around coping with pain and recuperation.

Days 3-14: Mainly self-care messages (one per day). The theme is around strategies and practical tips on pain and wound management.

Days 15-28: Coping and inspirational messages (one per day). The theme is still around coping with the wound and inspiring them and encouraging them to include their partners into the recovery period.

Days 29-42: Inspirational messages (tri-weekly). The theme is around offering alternatives to penetrative sex and inspiring them to complete the period penile penetration-free.

Study procedures: The study participants completed self-administered paper-and-pencil baseline surveys and then returned to the clinic or other convenient location, after six weeks to complete a follow-up survey. Participants who were allocated to receive the audio messages were loaded onto the platform by the project manager who passed the participants' cell-phone numbers, pin numbers and dates of enrolment to the m-health platform operator (a South African company Health Information Systems Program – HISP). The mobile system automatically called participants twice a day for the first two days, once a day for the next four weeks and on alternative days in the last two weeks. Using the last four digits of their mobile number as their password, the participant could listen to the message and, using their keypad, replay it if they did not understand the message. The platform was programmed to redial unanswered or busy numbers up to three times.

Sample size: We calculated that a sample size of at least 540 per arm, with a complete study sample of 1,080, would have 90% power to detect a 10% improvement in abstinence as found in previous studies, [17], [87]–[89] at 0,05 level of significance. The likely rate of loss to follow up was assumed to be 10% so the above numbers were adjusted accordingly and inflated by 10% to the effective total sample size of 1,188, or 594 per study arm.

2.4.4 Study IV

Study IV was nested within Study III, but only included participants from the intervention arm of the main trial who answered additional questions on the usability of the platform at follow-up and some of whom were recruited to focus group discussions. The quantitative part of the study used the usability survey data from the follow-up questionnaire for its analysis. The qualitative part was based on a convenience sample of 25 participants from the intervention Arm, constituting five focus groups. During the last two months of the study, whenever the participant completed the follow-up questionnaire and the study team quality-checked the completed survey, and found that the SUS scale was completed, they proceeded to recruit the participants for the usability focus groups. Using a convenience sampling method, 25 men who received the m-health intervention and completed the follow-up survey were recruited in this manner. Five focus groups were then conducted at the clinics between May and June 2016 with a total of 25 Coloured men from the Woodstock and Delft clinics. The participants' ages ranged from 18 to 54 (mean age 34).

The SUS usability scale: The SUS usability scale instrument was developed by John Brooke in 1986, as a reliable, low-cost usability scale that could be used for global assessments of

systems usability.[90] This scale, originally developed for the industrial engineering field, has since been applied to a wide variety of products and services, including hardware, software, mobile devices, websites and applications in the medical field.[91] The SUS has been evaluated for validity, reliability, and sensitivity, although not in the current population.[90]–[93] This 10-item Likert scale instrument is administered immediately after the conclusion of the intervention programme and allows users to record their initial feelings and responses about the programme. The ten questions are:

1. I think that I could use this system frequently
2. I found this system unnecessarily complex
3. I thought this system was easy to use
4. I think I would need the support of a technical person to be able to use this system
5. I found the various functions in this system were well integrated
6. I found there was too much inconsistency in the system
7. I would imagine that most people would learn to use this system very quickly
8. I found this system very cumbersome to use
9. I felt very confident using the system
10. I needed to learn a lot of things before I could get going with the system

The instrument items have a range of 0–4 and the scores range from 0 to 100 which provides a clear estimate of overall usability of the intervention.[90], [91] The scores were calculated according to scale's guidelines.[90] This consisted of summing the scores on each of the 10 individual items. The values of the negative items 2, 4, 6, 8, and 10, were subtracted from 5 and the positive items were reduced by one and the final sum of all scores was then multiplied by 2.5 to get the overall satisfaction value out of 100. Scores of above 68 are considered to be acceptable or good while scores of 85 or above indicate a high level of usability or excellent score. Scores of 50 or below indicate poor or unacceptable usability.[94]

Focus groups: The discussion guide was designed to gather information from the men on their opinions on the frequency and content of the messages, whether they found the tool itself as intrusive and whether it had any impact on their behaviour and attitudes.

All interviews were conducted in Afrikaans, tape recorded and then transcribed and translated into English.

2.5 ANALYSIS

2.5.1 Study I

We used a contextualized interpretive analysis[95], [96] to analyse the data of this study. This method is similar to a phenomenological approach, but accords high importance to context in understanding what emerges. All the interviews were read several times by the researchers so that a familiarity with the material could be established. On the basis of this familiarity, a set of themes were drawn out revolving around reasons for seeking VMMC, the experience around the procedure, the impact (short and long-term) of the procedure on relationships and

sexual behaviours (Appendix 7). After my initial familiarisation of the interviews, I drew up the draft set of themes that was then circulated between the other two authors who used it as a basis to confirm or challenge the inclusion or exclusion of theme items through meaning and interpretation. We used these themes to code the interviews with the assistance of Atlas.ti. Once the provisional analysis had been done all the interviews were reread, as a validity measure, to check for contradictory findings, and if any information had been inadvertently excluded. In the analysis, we acknowledge that using a male interviewer could have impacted the validity of the responses of the female participants. We have attempted to take this into account in the analysis.

2.5.2 Study II

Focus Groups: After capturing and translating the messages generated by focus group participants, the list was cleaned and common themes were identified through use of thematic analysis using Atlas TI.

The Health expert consultation process: As a first step, we grouped the messages into themes and then deleted incorrect, duplicate and repetitive messages. Through inter-rater agreement, we decided on one or two examples representing each theme. Several messages were also adjusted to reflect technical correctness and missing themes such as HIV prevention messaging. This decision was guided by existing theoretical models of behaviour change, including the HAPA Model. HAPA proposed a sequence of two continuous self-regulatory processes, a goal-setting phase (motivation) and a goal-pursuit phase (volition). The latter is further subdivided into a planning phase, action phase, and maintenance phase. It is claimed that perceived self-efficacy plays a crucial role at all stages along with other cognitions.[68] For example, risk perceptions, for example, a recurring STI infection, serve predominantly to set the stage for a contemplation process to go for a circumcision procedure. This is true early in the motivation phase but do not extend beyond. Similarly, outcome expectancies are chiefly important in the motivation phase when individuals balance the pros and cons of certain consequences of their behaviours, but they lose their predictive power after a personal decision has been made. However, if one does not believe in one's capability to perform a desired action, one will fail to adopt, initiate and maintain it. Therefore the drive for the messages to be relevant to the patient's crisis-management so it can tap into personal convictions later on in the recovery period. The order and frequency of the messages was guided by the recommendations of the focus groups, expert opinion and theory. This phase is essential to ensure the accuracy of the messages and their constructive interaction with the health services.

2.5.3 Study III

The statistical analysis plan was specified before the study was unblinded and was reported in the trial protocol published previously.[89] Analyses were undertaken on an intention-to-treat basis using SPSS[97] and Stata[98]. The primary outcome was the occurrence of penetrative sex at any time in the six weeks following the VMMC procedure. The primary analysis was

to detect a difference in proportions using an unadjusted binomial test. Additionally, generalized linear regression models for the analysis of binary outcomes were used to study the effects of the intervention as well as possible synergistic effects taking potential confounders into account if necessary, such as age, religion, marital status, education, employment and depression. The effect of the intervention was expressed as a relative risk (RR); a 95% confidence interval (CI) was used for primary and secondary outcomes.

The secondary outcomes were i) the adoption of non-penetrative sexual behaviours in the six weeks after the procedure, ii) the prevalence of self-reported STI symptoms, iii) the perception of sexual risk behaviour, and iv) the self-reported level of sexual risk propensity (as a measure of risk-taking personality). The penetrative sexual resumption rate was assessed using Kaplan–Meier survival analysis techniques: for 6-week follow-up data, resumption was assessed in participants who reported resumption of penetrative sex in weeks 1-3, week 4, week 5 and week 6.

2.5.4 Study IV

Focus groups: Similar to the analysis methods of study I and II, I used content analysis on the transcripts of the five focus groups to judge how the user experienced the m-Health tool. As first author of this paper, and who worked closely with the participants and was present during the interpretation, I undertook the initial analysis while the other co-authors who were not part of the data-gathering phase assisted with the interpretation of the results.

SUS usability scale: Statistical analyses were performed using IBM SPSS Statistics 24 for Windows.[97] All outcomes were inspected for normal distribution using histogram plots including normal curves and normal probability plots, and Shapiro-Wilk tests, prior to selection of appropriate statistical tests. Descriptive statistics (mean with standard deviation (SD) for normal distributed outcomes, or median with interquartile range (IQR) for non-parametric outcomes) were used to describe the participant characteristics and all outcome measures. A factor analysis using a Principal Component Analysis extraction method with a Varimax rotation, Cronbach alpha coefficient and χ^2 were computed.

3 RESULTS

Below I summarize the main results of the four studies but also include some process information that may add to the understanding of the main results.

3.1 STUDY I: UNDERSTANDING THE SEXUAL BEHAVIOUR OF MEN AND THEIR FEMALE PARTNERS AFTER VOLUNTARY MEDICAL MALE CIRCUMCISION

Reasons for seeking VMMC

In the first part of the study, we explored the reasons why men came to the clinics to be circumcised. Their primary motivation for seeking VMMC was threefold, it was either as a religious injunction, a strategy to prevent STI infection, or for health and cosmetic benefits. The men who converted to Islam as adults normally undergo the procedure within the first year after their conversion. The issue of free choice is very prevalent in this group. It appears that very few of the Muslim converts who came for VMMC do so it out of personal choice. They usually came because of religious injunctions, or at the insistence of the spouse's family or Imam. The issue of coercion is also expressed by men who are 'forced' to go for a VMMC procedure by health service provider. This lack of choice might influence the male's sexual behaviour over the six weeks as well as his unwillingness to adhere to rules including the non-penetration rule. A dominant reason for undertaking the procedure among non-Muslim participants was the issue of hygiene. Both men and women named the presence and smell of dirt and semen trapped under the foreskin as motivation. So the motivation might not be seen as a specific attempt to reduce STIs or protect against HIV infection, but there may have been a subliminal link to becoming disease-free.

Engaging in penetrative sex before wound healing

Many factors propel men to engage in penetrative sex before the required six weeks have passed. [99] Literature shows us that men in cohabiting relationships,[16] engage in penetrative sex before the recommended wound-healing period of six weeks has been completed. As described in the setting of the study population, couples live in fairly densely populated areas in small and cramped houses. Living together with very little interpersonal space, makes it difficult to avoid sexually laden situations so arousal and the need for sexual gratification gradually builds. Additionally, men felt pressure from the socially-induced fear of failing to satisfy their partners and therefore not maintaining the harmony of the relationship. In line with previous findings, some men did report penetrative sex during this period.

Sexuality and gender identities

In our study, we looked at the perceptions of men and their partners on having to abstain from penetrative sex in the six-week post-operative period and the effect this had on their relationships and the forms of non-penetrative sex practised and other ways of stabilising the relationship. This question spoke directly to the importance men and women place on the role of sex in their relationships. Men saw sex as a physical act that confirmed their masculinity, their role in the relationship and a mechanism to maintain the relationship. Women, on the

other hand, saw sex more as an affirmation of the relationship and their role to provide for the 'baser' needs of the man.

Penile function and sensitivity after VMMC

There were both positive and negative comments on penile function and sensitivity depending how old the respondent was (although the study was not designed to stratify by age). The younger participants had more positive comments. An exposed and desensitised penal gland meant that the man had more control over their ejaculations. Women also noted the ability of their partners to "hold out" longer after circumcision. The older respondents had more negative comments for virtually the same reason. In this case however, diminished sensitivity meant lower responsiveness and that influenced erectile duration and quality during sex.

3.2 STUDY II: DEVELOPMENT OF THE INTERVENTION

Step 1: Generation of messages and key information on the messaging

We ended up with a raw set of 245 messages that circumcised men and their partners felt would have had an impact on their behaviour and attitudes during the 42-day post-operative, wound-healing period. *Themes*

The messages suggested by the focus group participants dealt with very practical themes, such as wound and pain management, the role of rest and family support, erection issues, how to stay healthy, when to resume sex, alcohol use, affirmation, sexual needs of partners, and condom use. These themes were than further grouped into phases and practical versus motivational messages. The selection of messages covered the dominant areas of the HAPA theory, ie, Planning and its components of self-efficacy, goal setting and action (Appendix 7).

The two-phase approach

Our analyses indicated that participants divided the 42-day recovery period into a wound and pain management period (the first three weeks) followed by the adjustment period for the remainder of the period. The first phase was characterised by practical issues such as wound and pain management, while the second phase was dominated by motivational and planning issues.

Salutogenic nature of the messages

A strong preference towards positive and inspirational messages and not messages that emphasised disease and negative consequences were suggested by the groups.

Frequency of messages

Participants were wary of unsolicited and invasive messages and preferred a clear end date of the programme.

Step 2: Expert consultation

Together with the expert from the Provincial medical office, we reduced 245 messages to 56, by removing the duplicates and similar themed messages. These decisions were made with extensive knowledge of local knowledge of the population and local conditions and safe-sex and behaviour change. Table 7 shows the full set of themes by phase once all the messages were combined into a reduced set of thematic constructs, while remaining responsive to community felt needs.

Table 7: Themes and messages by phase after expert consultation

Phase	Themes	Examples of Messages
1	Inactivity and rest	*Rest! This will help with the wound healing.*
1	Role of the clinic; Wound management	*Go back to the clinic after two and seven days so the dressing can be replaced and the wound can be checked.*
1	Wound management; hygiene	*Use lukewarm water to wash the wound every day. Keep the dressing dry.*
1	Wound management; Erection issues	*Check for any skin tightness when you get an erection.*
1	Role of the clinic; Wound management	*If there is pus coming out of the wound, go to the clinic.*
1	Pain management; Medication	*Don't be brave! Take pain tablets to relieve the pain*
1	Wound management; Partner/Family support	*Are you having a difficult time? Talk to someone you love. They will understand.*
2	Self-efficacy & affirmation; Goal setting	*Want to be healthy? Look after yourself.*
2	Self-efficacy & affirmation	*You can do it!*
2	Partner/Family support	*Make sure you talk to your partner*
2	Self-efficacy & affirmation; Motivation	*Did you look after your penis today?*
2	Goal setting; Healthy living	*Regular exercise and healthy diet are essential*
2	Wound management; Erection issues	*Get rid of that painful erection by urinating frequently*
2	Early resumption of sex	*Having sex too early, will just set you back!*
2	Early resumption of sex; Alcohol consumption	*Be aware of alcohol. It impedes your judgement*
2	Safe living; Condom use	*Remember that circumcision does not provide 100% protection*
2	Motivation; Goal setting	*No sex or masturbation for six weeks!*
2	Non-penetrative sex; Sexual needs of partner	*Find ways to please your partner without using your penis*
2	Non-penetrative sex	*Loving is not about sex only!*
2	Self-efficacy & affirmation; Motivation	*You are the best!*
2	Motivation; Goal setting	*Regular condom use, knowing your HIV status and keeping to one partner is the recipe for an HIV-free future.*

Step 3: Cognitive interviews

We recruited twelve participants who engaged intimately with the messages and generally confirmed the set of themes proposed by the previous step except for the fact that former patients rejected some of the messages that were worded too technically or "preachy," thus reaffirming the initial focus groups' preference for more salutogenic messages. Their interaction with the messages originated from their own experiences during the wound-healing period and confirmed the elements of motivation and volition as proposed by the HAPA model. We separated the six-week period into three two-week periods for ease of rating and discussion.

Messages for the first two weeks: This period was dominated by pain and wound management themes and towards the end of this two-week period, the patient's support structure is also given priority. The respondents also recommended that the frequency of phone messages to patients should be twice a day at the beginning of the period, tapering to once a day after the first two days, to provide additional support for the days following the operation.

Messages for weeks three and four: The messages in this period reflect the changing priorities of the patient. The wound is for all intents and purposes healed and the patient is going through a period of how to adjust to this new body part, not only sexually, but also aesthetically and the way it felt.

Messages for weeks five and six: The high scoring messages in this period revolved around alternative sexual activity "*Loving is not about sex only!*" and validation, such as "*You lost the skin! Can you feel the difference?*" and looking-ahead messages, such as "*You are planning for your future*".

See Appendix 4 for the complete m-Health intervention messages.

3.3 STUDY III: EFFECTIVENESS OF THE INTERVENTION (RANDOMISED CONTROLLED TRIAL)

Between January 2015 and August 2016, 1,670 VMMC patients at twelve clinics were screened for inclusion into the study. 476 (28.5%) participants were excluded from the study prior to randomisation for the following reasons: 201 did not meet the inclusion criteria (142 patients were too young and 59 had no mobile phone), 216 were medically excluded from the VMMC procedure by the VMMC team, 48 were not interested in the study and 11 were excluded for other reasons. 1194 men (71.5%) were recruited into the study and randomised. After enrolment, 597 participants were randomised to each of the intervention and control arms. (See Appendix 11 for Consort diagram)

At the 42-day follow-up stage, the study could not collect data from 117 participants (9.8%). We followed up telephonically with this lost-to-follow-up group with a shortened questionnaire and we managed to obtain data from a further 61 (29 Intervention and 32 Control) participants. The data obtained from this cohort was incorporated into the main dataset. The remaining 56 loss-to-follow-up participants (4.7%) had similar pre-randomisation characteristics (Appendix 10). The follow-up study found that 31 participants were too busy to participate and 25 participants had moved from the area.

We found that exposure to the audio messaging system led to a modest decrease in the occurrence of penetrative sex compared to a control group who only received standard face-to-face care (28% vs. 32.3%), although the difference was not significant. We also found that the reporting of penetrative sex within the 6-week recovery period was associated with higher alcohol use and anxiety levels. We found a statistical trend suggesting that the presence of sexual risk factors such as the presence of at least one STI symptom and a self-perceived HIV

infection risk, as well as a high sexual risk propensity self-rating were independently associated with the higher incidence of penetrative sexual encounters during this period.

We also found that the level of sexual risk propensity has a greater effect on those who did not receive the intervention than those who did. The relative risk for sexual risk propensity was 3.91, which was the increase in risk for sexual activity with a one unit increase in propensity score for the control group. The interaction risk ratio was 0.197, which is the difference in risk ratios between the intervention and control groups (p=0.027). This means that the effect of the sexual risk propensity on early resumption of penetrative sex in the recovery period was different for the intervention and control groups. In the control group risk propensity increased the participants' likelihood of having sex, while in the intervention group there was minimal influence of risk propensity at baseline on early resumption of sex.

We found that participants who did not receive the audio messages had 26% less risk of engaging in non-penetrative sexual encounters in the post-op period compared to patients who received audio messages. This finding was statistically significant (p=0.009). While controlling for self-reported one or more penetrative sexual encounter in their recovery period and reported high sexual propensity risk scores, patients who did not receive the audio messages were 26% less likely of reporting one or more non-penetrative sexual encounter in their recovery period compared to patients who received audio messages. This finding was statistically significant (p=0.013).

We also conducted a survival analysis on the time to resumption of penetrative sex of the participants and found that there was no significant difference between the two groups (Log rank: 2.77, p: 0.096). The mean time to sexual debut in the intervention group was 5.81 weeks and in the control group it was 5.8 weeks. Amongst those who reported penetrative sex during the six-week recovery period, 48.2% of the intervention group and 50.9% of the control group engaged in sex between week 3 and week 5 of the recovery period. The remainder reported re-engaging in penetrative sex in week 6.

3.4 STUDY IV: MEASURING THE SATISFACTION AND USABILITY OF THE M-HEALTH INSTRUMENT

Message delivery

The mobile phone monitoring reports of the total number of calls that went out to all patients in the intervention arm indicated that 99% of scheduled calls went through, and 87.71% of these calls were received and acknowledged by patients (see section 4.2 below).

Usability scale

The SUS showed a good reliability and internal validity in the population.

The average SUS score for the whole group was 62.80 (SD 13.41) indicating a marginal satisfaction rating across these m-Health system users. However, wide variations in scores existed with a low value of 27.5 and high score of 87.5 with a range of 60-points. The spread

of the scores shows that 50% scored 60 points and below and the top third percentile scored 75 points and below.

On individual level, 207 (38%) participants rated usability over 70%, which means that the technology will have good to excellent chances for acceptance in the field, whereas 93 (17%) participants scored SUS below 50 % which indicates an intervention that will probably have usability difficulties.

We did not find any significant differences in the participants when we compared the usability rating scores with the main demographic variables of the men in the study. Foreign language users (86.0, 13.99) and room and garage dwellers (79.39, 13.02) had slightly higher usability scores than their counterparts.

Focus groups

The results of the focus group analyses are presented by the four topics explored in the discussions:

The frequency of the messages: Participants generally did not have an issue with the frequency of the messages because everyone knew what the programme was about.

The content of the messages: Most of the participants appreciated the narrow focus and contextual nature of the messages.

The perceived intrusiveness of the tool: The messages were short and infrequent enough to have the least impact on the participants' lives. There were some time clashes.

Reported impact on behaviour and attitude: Most participants felt that the messaging system had a positive outcome on their behaviour and attitudes, as they were dealing with the recuperation and health issues in the recovery period. The relevancy and frequency of the messages acted as judicious reminders to the recovering men, forcing them to reflect and plan their behaviour. As effective as the men found the programme, some of them did not adhere to the messages.

4 PROCESS ISSUES

4.1 FRONTLINE STAFF AND THE INTERVENTION

This study was designed to complement the excellent work done by dedicated frontline healthcare staff working in very difficult structural circumstances within the healthcare system. This self-care m-Health intervention aimed to add to the standard of care counselling regime that the VMMC patients receive in the VMMC clinics. It was not designed to substitute the counselling the patients receive before or after the surgical procedure in the clinic. Its primary goal was to pick up the patient from the time he leaves the VMMC clinic to the end of his 42-day wound recovery period. Therefore, from a systems perspective, this

intervention was designed not to interact with the healthcare frontline staff in the VMMC clinics, but rather, complement and shore up the counselling aspect of the VMMC care, after they leave the clinics, with the purpose of keeping the VMMC patient safe over the six-week recovery period.

Comments from my half-time seminar encouraged me to question the role and attitudes of health care staff on our intervention. Although we had of course discussed the goal and relevance of the intervention with leadership at the Provincial Medical Office, we had not systematically interviewed health care staff. Therefore, in February 2016, I interviewed the Head Surgeon of the VMMC team in the Central and Southern Sub-structure for the entire study period. I asked him what he thought of the intervention and the goals it set for itself.[100] He was very complimentary of the intervention and went into detail of the emergency cases they were getting with torn stitches and penile infections within the first three weeks following surgery and penile tearing during the last three weeks of the recovery period. He acknowledged that the current system was geared more towards the surgical aspect of the VMMC process rather than what the patient does afterwards. He said that in the beginning of the VMMC drive after 2010, the typical patient that came in for circumcision were self-motivated and therefore more aware of the processes that needed to be completed. These were typically older men that wanted to be circumcised in the first place, so the health talk on the day of the surgery was easy and the safety points that had to be covered were transferred much easier, because these men listened. He felt that some difficulties crept into the system when the numbers of the traditional self-motivated patients started to dip and DoH appointed community mobilisers to actively recruit men in the communities to be circumcised. Dr Hartley felt that this recruitment process brought another type of men into the process. They were usually younger, mostly unemployed and, in many cases, had not really thought the circumcision process through. In his opinion, these men had a more difficult time on the day of the surgery. Many of them were under the impression that the surgery was “just a minor inconvenience” and they could go back to their busy and active lives. He estimated that 90% of the emergency comebacks were that of men who simply did not hear anything they were told to do. He suggested that we not only target no sex behaviour, but expand it to include all the wound-recovery messages that are given before surgery.

I also participated in a feedback workshop at the end of the fieldwork phase with nursing staff at Elsies River Clinic in the Northern Sub-structure. They had the same comments that the Head Surgeon made. Additional comments were that they sometimes had difficulties with our study in the clinic as they had to wait for the patients to complete the questionnaires which they felt was too long and were putting the patients under stress. When prompted how often this occurred, the nurse conceded that did not happen frequently. The general staff that received the men on days 2, 7 and 14 in the wound recovery section, did not know about the study nor did they hear anything being said by the patients about the study. When asked whether they reinforced any behavioural messages at those three consultation sessions, the

answer was negative because they only concentrated on wound management. They also supported the idea that the messages should be more wound-management centred.

4.2 FIDELITY OF THE INTERVENTION

A high level of intervention fidelity was maintained during the trial. The mobile phone monitoring reports of the total number of calls that went out to all patients in the intervention arm indicated that 99% of scheduled calls went through, and 87.71% of these calls were received by patients (Table 5). In addition, at an individual level, the patients in both arms who did not present at the follow-up data collection point were contacted telephonically and asked about the reasons for the drop out. In addition, 62 of the 117 lost to follow-up patients filled in a shortened questionnaire around the main outcome variables. There were no reported adverse events associated with phone use, and using the Systems Usability Scale, the participants scored out a range from 0 to 100, a mean of 76.72 (13.223).

Table 5: Percentage of access to intervention messages

Day	Message	Accessed (%)	SD
1	rest helps with healing	92.1	0.270
1	rest helps with healing 2	85.4	0.353
2	keep appointment schedule	96.3	0.189
2	bath. Keep dressing dry	76.5	0.424
3	lukewarm water	87.6	0.330
4	talk to someone	81.6	0.388
5	no pulling or scratching	92.5	0.264
6	clinic: meds not working	72.9	0.445
7	clinic: difficult urinating	85.1	0.356
8	clinic: pus out of wound	77.7	0.416
9	clinic: fever	80.2	0.399
10	clinic: abdomen pain	91.5	0.280
11	skin tightness during erection	85.4	0.353
12	look after yourself	87.8	0.328
13	clinic: bleeding	86.9	0.337
14	VMMC not 100% protection	91.0	0.287
15	involve partner in recovery	86.4	0.343
16	think before you do	93.7	0.250
17	just a few weeks more	89.7	0.310
18	early sex will set you back	82.6	0.380
19	please your partner	93.0	0.256
20	exercise and diet	91.0	0.287
21	you can do it	94.3	0.232
22	be proud of yourself	98.2	0.135
23	early sex will set you back 2	85.4	0.353
24	urinating helps with erections	88.9	0.314
25	take pain tablets to relieve the pain	86.3	0.345
26	look after your penis	95.3	0.212
27	no sex or masturbation	88.9	0.314

28	be aware of alcohol	84.4	0.363
29	listen to your partner	84.6	0.361
30	early sex will set you back 3	85.8	0.350
32	Loving is not only sex	87.8	0.337
34	You did it	86.9	0.287
36	Target healthier body	91.0	0.343
38	Don't need penis for loving	86.4	0.250
40	Restraint will be rewarded	93.3	0.310
42	HIV-free recipe	89.3	0.337

5 DISCUSSION

This discussion is divided by what I see as the most important findings and contributions from the study4. This is followed by a discussion of the ethical and methodological considerations that the reader should bear in mind.

VMMC is practiced for different reasons

Circumcised men and their partners in the Coloured communities of Cape Town had a variety of primary motivations for undergoing VMMC. Those who did it because others required/requested it (due to conversion to Islam or because of frequent STIs), spoke about external coercion that was either social in the case of religious conversion, or medical in cases of STI infections. This externalisation of choice could have a substantial amount of influence on how they approach the strict treatment regime especially during the first two weeks into the recovery period, and the restrictions on penetrative sex in the last part of the recovery period.

Nobody in our study explicitly said that HIV prevention was the reason why they wanted to be circumcised, but both men and women cited hygienic reasons such as the presence and smell of dirt and semen trapped under the foreskin, as a strong motivation to be circumcised. Cleanliness is often seen as being the opposite of diseased,[101] so there may have been a subliminal link to becoming disease-free. Responding to the direct question of whether they thought that VMMC was a protective barrier against HIV infection was a good thing, most of them responded positively to the idea, although we surmise that the HIV infection barrier was a 'nice-to-have' rather than to motivate as a primary reason. With a rising HIV prevalence in the Coloured population, and the study participants' stated aversion to regular condom use,[102] there remains a heightened risk to HIV and other STI infections. The stigmatic phenomenon of ascribing the HIV epidemic as a 'Black' disease or a disease that is ravaging everywhere in South Africa except in the Western Cape, serves to perpetuate undue risky behaviour within the community. The fact that they really do not see themselves at risk of HIV, is a particular source of concern, given the generalized nature of the epidemic in the Coloured population. On the other hand, in a study conducted in 2012 in urban Swaziland,

they found that male circumcision fostered a protective behaviour change in the patients and found them with a more responsible attitudes towards safe sex and easier condom use.[99]

Sex is important for couples from a gender identity perspective

The focus group discussions indicated that both men and women in this population saw the sexual act, not only as a biological need, but also as a social tool in relationship maintenance. Although men were perceived to be more sexual than women, both viewed sexual activity as a measure of who they are in terms of gender as well as using it to gauge marital success. This is an important point to remember for programme developers when they look at how couples negotiate the six-week abstinence period, particularly the last two weeks when the penile wound has healed to the extent that it does not present a medical barrier. Non-penetrative sexual activity, such as rubbing, mutual masturbation, kissing or cuddling are used as alternative to penetrative sex, but there was a general feeling among male participants that it was a poor substitute for 'real sex'.

Ensuring the relevance of messages requires participative methods

The study showed us one method to compile a relevant programme is to directly engage men and their partners in iterative discussions about message design and delivery and involve them in the development of messages so that messages are relevant and meaningful for the recipients.

A few studies have utilised a multi-phased approach with a strong target group participation to construct and develop m-Health messages. Ybarra and team (2015) designed an m-Health HIV prevention program for adolescent gay, bisexual, and queer men, by taking the message development through five iterations with target audiences contacted in the first phase to test acceptability of the messages and during the last phase with beta testing. They found, as in our study, that participants preferred positive and friendly content that does not sound that it is delivered by a teacher.[70] Similarly, Jensen and colleagues (2016) explored obese adolescent participants' perspectives related to weight management messages, and they found enthusiasm for SMS messages that were brief, positive, encouraging messages that had a 'natural' tone and made specific reference to the teen demographic, as a strategy to support weight loss efforts among these participants.[103], [104] Another m-Health weight management programme conducted by Hindle and her team in 2013 also using a multi-stage youth participatory approach, found similar results.[72] The main difference of our study to the ones mentioned above, is that the source of the messages in our study came from the target audience as opposed to researchers and experts. This resulted in a fairly good usability rating in our study. Although we cannot know if usability would have been lower without participation from former patients and their sexual partners, action research theory strengthens our argument that meaningful interventions are co-developed with the target group.

Using behavioural change theories can strengthen messaging

There is a paucity of studies that use behavioural change theory in the development of messages. To develop and test messages to influence the knowledge, attitudes, and behaviour of adolescents on nutrition and physical activity, Hingle et al (2013) used a 3-phased youth-participatory approach. The first phase was the identification of content and initial message

development by content experts and experts in the field, the second was message testing and refinement that was done with a sample of the target audience and the last phase was pilot-testing of a message delivery protocol.[72] Other similar studies by Bock [71] and Yberra [70] concluded that partnering with the target population in the message development phase is critical to ensure that a salient and relevant final product is produced. The salutogenic versus the pathologic nature of the messages has also been shown as a deciding factor in the rate of acceptance of the m-Health interventions.[105], [106]

Our study used a participatory approach to take the opinions of the target population in the development of the messages and the frequency of messages into account. The first phase of involvement was at the generation of the messages, followed by the reflection of expert opinion on these messages. Finally, a group of recently circumcised men was used to test a cleaner and more theme-centred set of messages for relevance and impact.

The focus groups told us that the recovery period of 42 days following the VMMC procedure is not a homogenous period. Rather, we had to think of it as a series of progressive phases flowing naturally into each other. The first phase is one of survival. From the purely physical pain and trauma to the only issue in the early phase, which is wound management healing. The next progression is that of adjustment, to how their circumcised penis was looking and feeling, and realigning their attitude towards this new feature in their lives. The last phase is dominated by an external adjustment to physical movement and sex drive. The content of the messages needed to reflect this continuous movement through the 42 days. The progression of the messages followed this pattern, from the more practical messages, centred on pain and wound management, to more inspirational and “planning-ahead” messages at the end of the recovery period.

We found that applying this theoretically informed approach carefully, resulted in message content that was consistent across different recuperation phases. We made sure that the messages fitted into the existing standard of care regime offered by the clinic, from the three sessions to check the wound and change the dressing to encouraging them to use clinic services in case of medical emergencies.

Patients are more interested in salutogenic messages

A compelling finding of the study was that there was a strong consensus that salutogenic and caring messages have a better impact on behaviour change than pathological ones. The salutogenic model is useful for health promotion as it provides a clear direction and focuses on the entire person in relation to the disease.[105] We found that the messages that health communication experts considered as essential knowledge and skills for circumcised men to navigate their wound-healing period successfully, such as standard condom-use and HIV prevention messages, scored consistently low in desirability and impact. This could be because the messages were addressing irrelevant issues of the target audience as most of the participants went to be circumcised for reasons other than HIV prevention. Another reason for their low scoring could be that there is a perceived over-saturation of theis type of messages and the low scores merely represents a natural pushback.

The voice message system did not have a significant effect on penetrative intercourse in the recovery period

To our knowledge, this was the first randomized trial to evaluate an audio messaging m-Health system to improve post-operative counselling to recovering VMMC patients. We found that exposure to the audio messaging system led to a modest decrease in the occurrence of penetrative sex compared to a control group who only received standard of care (28% vs. 32.3%), although the difference was not significant. This non-significant result could point to the fact that m-Health strategies cannot be used in isolation to effect behaviour change, suggesting that they must be used in conjunction with other counselling and support programmes to safeguard men's health during this recovery period.

The intervention may be effective for high-risk patients

Our study showed a clear interaction effect between the probability of engaging in sexual activity early and sexual risk-taking personality of the control group who did not receive the m-Health intervention. Thus, the intervention seems to have been effective in reducing risk-taking behaviour amongst men with higher risk at baseline. This indicates that if VMMC patients were screened for risk-taking behaviour at the pre-operative phase, the intervention could potentially be offered only to those who display a sexual risk-taking personality and that could prevent even riskier behaviour than what we saw amongst those who received the intervention.

Early resumption of sex in the recovery period is a fact

About one-third of the study population resumed sex before the WHO-recommended time limit of six weeks and nearly 50% of those who reported engaging in penetrative sex during the recovery period had sex before week five. Amongst those who reported penetrative sex during the six-week recovery period, 48.2% of the intervention group and 50.9% of the control group engaged in sex between week 3 and week 5 of the recovery period. Thus, the issue of early resumption of sex, as indicated by previous studies in other countries in the region, is a fact in South Africa and still needs to be addressed.

The intervention platform had medium to low usability score

Ourm-Health platform was rated medium to low on a usability scale, with a scale mean of 62.80, which is below the industry-standard usability mean score of 68.[93] The low score confirms that the intervention needs to be adjusted and improved. On the other hand, the qualitative responses indicated that participants generally received the frequency of the messages positively due to their pre-knowledge of the rate of the message delivery before the programme started. The men also found the use of the technology easy to cope with. The messages were generally perceived as relevant because we designed in such a way that the timing of their delivery coincided with specific health or recuperation issues the men were grappling with. This relevancy-rule matches other m-Health intervention literature that proposes that the content of the intervention needs to be better adapted to a suit wide variety of users in order to facilitate a wider usage for a larger number of users.[107]

5.1 METHODOLOGICAL CONSIDERATIONS

We spent much effort and time during the project's planning stage to ensure that our study was rigorous, valid, reliable, and actionable. We found it markedly easier to apply these

expectations to the quantitative phases of the overall project, but not so much to the qualitative stages.

5.1.1 Qualitative data

In this section, I will outline the steps we took to ensure an acceptable level of trustworthiness[108] of our qualitative data. I will use the following criteria set out to evaluate qualitative research: dependability, credibility, transferability and confirmability [108][109][110]

The dependability of the data: This refers to the stability of the data from the time it was collected in the field to when it is synthesised and interpreted in study reports and articles.[110]. Schwandt et al. recommends the following strategies:[111]

- *An audit trail:* We have kept detailed records of all focus groups and interview transcripts, observational fieldwork notes, fieldwork activities and administrative forms, to allow an auditor to conduct a thorough audit trail. These records are available on request. (*also see:* Confirmability)
- *Stepwise replication:* All of the qualitative data was analysed by myself, but all of the data was checked by the two principal investigators.
- *Triangulation:* This strategy was used in Study I where we collected data from the VMMC patients and then from their partners using identical questions and probes. In Study II, we retested the data taken from the focus groups with a cohort of single in-depth interviews. (*also see:* Credibility)
- *Peer examination/peer debriefing:* I received feedback on all the raw transcripts, coding frame and interpretation by the two principal investigators of the study. The content expert from the Department of Health also provided valuable feedback in Study II.

The credibility of the data: Credibility is defined as the confidence that can be placed in the truth of the research findings.[111] The credibility criterion looks at whether the conclusions the study makes is congruent with the original data collected from the participants in the field.[111] The following strategies are recommended:[108]

- *Prolonged engagement in field or research site:* I was working with the participants for two years in the field and understood the circumstances and the environment the study participants come from. The fieldworkers are from the same area, they speak the same language and all of them have extensive fieldwork experience beyond the study.
- *Use of peer debriefing:* I had regular feedback sessions with the PIs where I presented fieldwork reports for feedback to improve the quality of the data. The study also had a mid-study auditor who looked at the data collection methods and process, data management, transcripts, data analysis procedure and research

findings. The researcher also presented the data to the DoH team who also provided feedback to the study.

- *Triangulation:* (See the dependability strategies above)
- *Member checks:* I only used this strategy in Study II when I tested the complete message system with the 12 VMMC patients.
- *Negative Case Analysis:* Going through the interviews again revealed few contradictions with the analysis. Where minor conflicts occurred these were reformulated.
- *Persistent Observation:* I was assisted in understanding the nuances of the participants' remarks and observations by u my research experience with this population and in this context, and the fact that I am of the same ethnic background.

The transferability of the data: This strategy refers to the degree to which the results of qualitative research can be transferred to other contexts or settings with other respondents.[112] The following strategies are appropriate:[108]

- *Provide thick descriptive data:* This strategy required me to expand and explain all the research processes of the study. From the data collection,and the context of the study to production of the final report. The thick description helps other researchers to replicate the study using similar conditions in other contexts or settings. The research team has successfully transferred this programme to a similar study in Bloemfontein, Free State.

The confirmability of the data: This strategy refers to the degree to which the results of the inquiry could be confirmed or corroborated by other researchers. There is only one strategy recommended:

- *Practice reflexivity/reflexive journal:* I have kept a fieldwork diary throughout the fieldwork and analysis phases, documenting personal reflections in relation to the study such as ethical dilemmas and 'aha' moments that arose during the process of the investigation.

By following these guidelines and strategies, I feel that I have fulfilled and completed all the strategies to ensure that my qualitative study remains trustworthy.

5.1.2 Quantitative data

External validity

Study population: Participants in the study are no different from the general population they come from in the communities located in the catchment areas of the healthcare clinics. We recruited all the types of VMMC clients, walk-ins, clinic recruited and community mobiliser recruited. The study's eligibility and exclusion criteria were designed in such a way to retain

all men 18 or older who indicate at the pre-counselling session that they a) possess a mobile phone, and b) consent to participating in the study.

Study decliners: Out of the 1670 VMMC patients at 12 clinics that were screened, only 1194 men (71.5%) were recruited into the study and randomised. 476 (28.5%) patients were excluded from the study (Appendix 11) for a variety of reasons. The demographic features of the 48 (2.9%) eligible participants who declined to participate in the study were similar to the main study cohort. (Appendix 12)

The advantage of a controlled study is that both the control and intervention groups are interviewed an equal number of times so there will not be any so-called Hawthorne effect. There may be more motivation to change behaviour simply by receiving phone messages (as opposed to the content itself) but if this changes behaviour then this is an acceptable public health outcome.

Internal validity

The study was conducted with rigor and sought a high degree of internal validity by the random assignment of the intervention, with pre-specified blinded analysis. The performance of the intervention was monitored over the duration of the study period and the fidelity was high.

Missing participants: We compared the demographic profiles of our loss-to-follow-up cohort and I did not find significant difference between them and participants who completed the study. (Appendix 10)

Item reliability in the SUS scale: In study IV, we tested the internal reliability of the scale items and obtained an overall Cronbach's alpha score of 0.648. Three factors loaded prominently (Eigen value >1) and explained 67% of the variance and revolved around the usability and learnability of the scale.

5.2 ETHICAL CONSIDERATIONS

The three fundamental principles of research ethics – Respect, Beneficence, and Justice – are upheld in this study through the following processes: The design and use of an ethically approved informed consent form, the adherence to a completely confidential enrolment procedure and documentation system, and all research staff went thorough ethical training and Good Clinical Practice certification.

The study had to navigate several ethical issues. The first one was its target audience in Cape Town. It used members of the Cape Coloured community at the exclusion of members of the Black community who have traditionally been pegged as the higher risk to HIV infection. The reason for this inclusion criterion is that the majority of Blacks in the City of Cape Town municipality area are from the Xhosa-speaking community who practice male circumcision in traditional ceremonies and thus do not seek it in large numbers from clinics. For the purpose of the study, the study population being essentially homogeneous worked in the

study's favour. Once the intervention's efficacy has been proven, cultural adjustment could be made to the content of the messages to target this grouping.

Another ethical dilemma is that one of the exclusion criteria includes not having a cell phone and the sexual risk profile of lower economic status communities is well published. Also, due to legal and logistical reasons, the study also excluded persons under the age of 18, where research has shown that sexual risk behaviour starts at an earlier age. The study found that the possession of a mobile phone as an inclusion criterion is central to the delivery of the m-Health intervention. Studies have shown us that the penetration of mobile phones, especially in this population demographic, is nearly universal. Our study reported that out of the 1125 participants approached to participate on the study, we only had to exclude 16 participants for not having a mobile phone. With regards to the age limitation, we acknowledge that risk to HIV and other STI exposure is not restricted to a legal-age status, but the ethical procedure for recruiting minors would have necessitated an additional tier in the study population.

The study proposes, as per RCT conventions, to introduce the behaviour intervention to only the randomly selected intervention group with no plans to offer it to the control group for obvious logistical reasons. It remains, however, an ethical dilemma that a group with the same risk profile as those receiving the intervention are denied access to it. This a regrettable ethical issue as the intervention is time-bound and it is not possible to offer it to the control group after exiting the study since they will already have passed the 6-week message period.

The last ethical issue the study had to grapple with is that participation incentives were given to the participants at the baseline assessment phase ($7) as well as when they come back for the post-intervention assessment ($10). The question being raised is that, with the study being conducted in a generally poor community, whether the incentive constituted an undue pressure for study participants to participate. The challenges of incentivising participants for participating in research are very well documented and debated. We follow GCP guidelines on this matter and we make sure that the participants are very well informed of their rights when they are recruited into the study. The ethics committee of the University of Stellenbosch determined that the amount was not coercive in this setting.

Ethical approvals

Study I and II: The study was approved by the Stellenbosch University Health Research Ethics Committee (Reference Number: N13/02/018) and was accepted by the Western Cape Department of Health (Reference Number: RP 100/2013). The identity of all participants remains confidential. All respondents gave written informed consent prior to the interviews. All transcripts have had all personal details of the respondents removed. Copies of all the interviews are held only on password protected computers.

Studies III and IV: in addition to the internal ethical approvals for the conduct of the trial were obtained from all participating institutions prior to study initiation (The Health Research

Ethics Committee of Stellenbosch University - ref N14/08/108) and is registered in the Pan-African Clinical Trial Registry (PACTR201506001182385).

Access to the participants was obtained at the clinics through the provincial department of Health (Reference: RP 100/2013). Written informed consent was obtained from all participants prior to enrolment as required with national requirements and the principles of the Declaration of Helsinki. Confidentiality was maintained at all levels of data management. An independent data safety and monitoring inspection was performed midway through the trial. All staff who came into contact with participants completed a GCP/ethics course. Compliance with GCP was confirmed by an external clinical monitor in the first six month of the study.

6 POLICY IMPLICATIONS

This study suggests that messages to men in the post-operative period after VMMC should address the reality and crises the men are facing throughout the six-week period, as they are experiencing them. They must also be positive in nature and not use scare tactics to force compliance. The messages must be bite-sized and simple to understand. The men constantly gave complex and compound messages a low ranking. The messages must also be culturally appropriate for the intended audience. An important aspect of message relevance was that it was linked to frequency and rate of delivery. An effective and relevant message system contained well-timed simple messages that were few in number and had a finite delivery period.

The fact that, even after careful pre-trial planning around the needs and requirements of the target audience and the clinical environment, the development of a theory-based, participant-driven m-Health programme and a rigorous and robust trial methodology, the positive effect of the intervention remained statistically non-significant, tells us that m-Health strategies cannot be used in isolation to effect behaviour change. In this instance, it must be used in conjunction with other counselling and support programmes to safeguard men's health during this recovery period. It is essential to recognise that the potential of m-Health programmes in developing countries' healthcare systems. We need to see mobile technology as a potential tool in the development of effective public health intervention programmes, especially in resource-strapped environments.

Post-operative counselling strategies must be tailor-made to the participants they are targeting. If patients with high risk-taking personalities can be identified through the VMMC clinical uptake procedures via a brief 3-5 item questionnaire, these patients could then be enrolled in more intensive and sustained counselling sessions.

The study also identified the specific weeks in the recovery period that patients reported most of the sexual incidences. Weeks 5 and 6 accounted for 88% of the incidences of early penetrative sexual encounters. Targeted programmatic interventions could be designed to

concentrate on this period of the VMMC patients' recovery period taking into account the pressures that men feel to engage in penetrative sex during this time.

This study demonstrates an effective way in which to engage men in the development of their own health interventions. Rather than being passive recipients of ''top-down,'' expert-driven communications, participants in this study had the opportunity to actively participate in the message design process and engage with health information through informal interactions with experts and with one another, thereby increasing the likelihood that they adopted the recommended behaviours. Based on our findings, this methodological approach to the development of theory-driven, evidence-based, and culturally appropriate health messages in mobile health interventions could be adapted to other cultural and geographic environments and various health issues. This can be used as a model to test and adapt health messages in a variety of mobile health intervention projects within a variety of cultural contexts. It can also be applied to health communication message development more generally.

Additional research is needed to determine whether this approach facilitates technology-based interventions to be an effective, sustainable way to promote healthy lifestyles to circumcised men and have a significant impact on behaviours that place men at increased risk. The overall results also raise the question of whether interventions such as these need to rather form part of a more systematic intervention rather than being seen as an individual input into the system of influences on men in this context.

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8 REFERENCES

[1] UNAIDS, “Core Epidemiology Slides; 2016,” *AIDSinfo website*, 2016. [Online]. Available: http://aidsinfo.unaids.org/. [Accessed: 01-Apr-2017].

[2] UNAIDS, “HIV/AIDS Fact Sheet, 2016,” 2016. [Online]. Available: http://www.unaids.org/en/resources/fact-sheet. [Accessed: 23-Apr-2017].

[3] UNAIDS, “The Gap Report,” Geneva, 2014.

[4] UNAIDS, “Prevention Gap Report - UNAIDS 2016,” Geneva, 2016.

[5] SANAC and National Department of Health, “Global Aids Response Republic of South Africa,” Geneva, 2012.

[6] WHO, “WHO Statistical Information System,” *WHO Statistical Information System*, 2013. [Online]. Available: http://apps.who.int/gho/data/node.country.country-ZAF?lang=en. [Accessed: 23-Apr-2017].

[7] J. E.-O. Ataguba, “Health Care Financing in South Africa: moving toward universal coverage,” *Contin. Med. Educ.*, vol. 28, no. 2, 2010.

[8] South African National Department of Health, “The 2012 National Antenatal Sentinel HIV & Herpes Simplex type-2 Prevalence Survey, South Africa, National Department of Health,” pp. 1–86, 2013.

[9] T. Makombo, “Fast Facts: Public health sector in need of an antidote,” Pretoria, South Africa, 2016.

[10] M. Mbali, “AIDS Discourses and the South African State: Government denialism and post-apartheid AIDS policy-making,” *Transform. Crit. Perspect. South. Africa*, vol. 54, no. 1, pp. 104–122, 2004.

[11] P. Chigwedere, G. R. Seage, S. Gruskin, T.-H. Lee, and M. Essex, “Estimating the lost benefits of antiretroviral drug use in South Africa.,” *J. Acquir. Immune Defic. Syndr.*, vol. 49, no. 4, pp. 410–5, Dec. 2008.

[12] WHO, “Manual for Male Circumcision under Local Anaesthesia,” Geneva, 2009.

[13] R. Zulu, D. Jones, N. Chitalu, R. Cook, and S. Weiss, “Sexual Satisfaction , Performance , and Partner Response Following Voluntary Medical Male Circumcision in Zambia : The Spear and Shield Project,” *Glob. Heal. Sci. Pract.*, vol. 3, no. 4, pp. 606–618, 2015.

[14] WHO, “WHO/UNAIDS Technical Consultation on Male Circumcision and HIV Prevention: Research Implications for Policy and Programming New Data on Male Circumcision and HIV Prevention: Policy and Programme Implications,” Montreux, 2007.

[15] M. J. Wawer, F. Makumbi, G. Kigozi, D. Serwadda, S. Watya, F. Nalugoda, D. Buwembo, V. Ssempijja, N. Kiwanuka, L. H. Moulton, N. K. Sewankambo, S. J. Reynolds, T. C. Quinn, P. Opendi, B. Iga, R. Ridzon, O. Laeyendecker, and R. H. Gray, “Circumcision in HIV-infected men and its eff ect on HIV transmission to female partners in Rakai, Uganda: a randomised controlled trial,” *Lancet*, vol. 374, pp. 229–237, 2009.

[16] A. Herman-Roloff, R. C. Bailey, and K. Agot, “Factors Associated with the Early Resumption of Sexual Activity Following Medical Male Circumcision in Nyanza Province, Kenya,” *AIDS Behav*, vol. 16, no. 5, pp. 1173–81, 2012.

[17] P. C. Hewett, T. B. Hallett, B. S. Mensch, K. Dzekedzeke, S. Zimba-Tembo, G. P. Garnett, and P. E. Todd, “Sex with stitches: the resumption of sexual activity during the post-circumcision wound healing period in Zambia,” *AIDS*, vol. 26, pp. 0–0, 2012.

[18] E. E. Chigondo, “A Study To Assess The Acceptance Of Male Circumcision As A Preventive Method In Hiv And Aids , In Mbare And Southerton Suburbs Of Harare , Zimbabwe,” *Res. J. Soc. Sci. Manag.*, no. May, pp. 123–130, 2014.

[19] S. D. Mehta, R. H. Gray, B. Auvert, S. Moses, G. Kigozi, D. Taljaard, A. Puren, K. Agot, D. Serwadda, C. B. Parker, M. J. Wawer, and R. C. Bailey, “Does Sex in the Early Period After Circumcision Increase HIV- Seroconversion Risk? Pooled Analysis

of Adult Male Circumcision Clinical Trials," *AIDS*, vol. 31, no. 2312, pp. 1557–1564, 2009.
[20] J. H. Rogers, E. Odoyo-june, W. Jaoko, and R. C. Bailey, "Time to Complete Wound Healing in HIV-Positive and HIV-Negative Men following Medical Male Circumcision in Kisumu , Kenya : A Prospective Cohort Study," *PLoS One*, vol. 8, no. 4, pp. 3–9, 2013.
[21] S. Macfarlane, M. Racelis, and F. Muli-Muslime, "Public health in developing countries," *Lancet*, vol. 356, no. 9232, pp. 841–846, 2000.
[22] C. Free, G. Phillips, L. Felix, L. Galli, V. Patel, and P. Edwards, "The effectiveness of M-health technologies for improving health and health services: a systematic review protocol," *BMC Res. Notes*, vol. 3, no. 1, p. 250, 2010.
[23] A. Chib, M. H. van Velthoven, and J. Car, "mHealth adoption in low-resource environments: A review of the use of mobile healthcare in developing countries.," *J. Health Commun.*, vol. 730, no. March 2014, pp. 1–46, 2014.
[24] S. Holubar and L. Harvey-Banchik, "A review of the use of handheld computers in medical nutrition," *Nutr Clin Pr.*, vol. 22, no. 4, pp. 428–435, 2007.
[25] A. Kho, L. E. Henderson, D. D. Dressler, and S. Kripalani, "Use of handheld computers in medical education," *J. Gen. Intern. Med.*, vol. 21, no. 5, pp. 531–537, 2006.
[26] W. H. Curioso and P. N. Mechael, "Enhancing 'M-health' with south-to-south collaborations," *Heal. Aff*, vol. 29, pp. 264–267, 2010.
[27] Vital Wave Consulting, "mHealth for Development: The Opportunity of Mobile Technology for Healthcare in the Developing World," *Technology*, vol. 46, no. 1, pp. 1–70, 2009.
[28] P. Mechael and S. Searle, "Barriers and Gaps Affecting mHealth in Low and Middle Income Countries : Policy White Paper," *Heal. San Fr.*, vol. 54, no. March, pp. 1–79, 2010.
[29] K. Banks and R. Burge, "Mobile Phones: An Appropriate Tool For Conservation And Development?," in *Fauna and Flora International*, 2004, pp. 1–67.
[30] J. Donner, "Research Approaches to Mobile Use in the Developing World: A Review of the Literature," *Inf. Soc.*, vol. 24, no. 3, pp. 140–159, 2008.
[31] J. Wei, I. Hollin, and S. Kachnowski, "A review of the use of mobile phone text messaging in clinical and healthy behaviour interventions," *J. Telemed. Telecare*, vol. 17, no. 1, pp. 41–48, 2011.
[32] N. Harding, *The Mobile Marketing Association of South Africa's Annual Digest 2014*. Johannesburg: Standard Bank of South Africa, 2014.
[33] T. Crankshaw, I. B. Corless, J. Giddy, P. K. Nicholas, Q. Eichbaum, and L. M. Butler, "Exploring the patterns of use and the feasibility of using cellular phones for clinic appointment reminders and adherence messages in an antiretroviral treatment clinic, Durban, South Africa.," *AIDS Patient Care STDS*, vol. 24, no. 11, pp. 729–734, 2010.
[34] K. Mukund Bahadur and M. PJ, "Cell phone short messaging service (SMS) for HIV/AIDS in South Africa: a literature review," *Stud. Heal. Technol. Informormation*, vol. 160, no. 1, p. 530–4., 2010.
[35] L. Filderman, "Project Masiluleke A Breakthrough Initiative to Combat HIV/AIDS Utilizing Mobile Technology & HIV Self-Testing in South Africa," Johannesburg, 2011.
[36] T. De Jongh, R. Atun, and J. Car, "Mobile phone messaging reminders for attendance at healthcare appointments (Review) SUMMARY OF FINDINGS FOR THE MAIN COMPARISON," no. 12, 2013.
[37] R. Guy, J. Hocking, H. Wand, S. Stott, J. Kaldor, H. Ali, and J. Kaldor, "How Effective Are Short Message Service Reminders at Increasing Clinic Attendance ? A Meta-Analysis and Systematic Review," *Health Serv. Res.*, vol. 47, pp. 614–632,

2011.
[38] M. Vervloet, a. J. Linn, J. C. M. van Weert, D. H. de Bakker, M. L. Bouvy, and L. van Dijk, “The effectiveness of interventions using electronic reminders to improve adherence to chronic medication: a systematic review of the literature,” *J. Am. Med. Informatics Assoc.*, vol. 19, pp. 696–704, 2012.
[39] J. Peter, P. Barron, and Y. Pillay, “Using mobile technology to improve maternal, child and youth health and treatment of HIV patients,” *South African Med. J.*, vol. 106, no. 1, pp. 3–4, 2016.
[40] D. J. Finitsis, J. A. Pellowski, and B. T. Johnson, “Text Message Intervention Designs to Promote Adherence to Antiretroviral Therapy (ART): A Meta-Analysis of Randomized Controlled Trials,” *PLoS One*, vol. 9, no. 2, 2014.
[41] H. Cole-Lewis and T. Kershaw, “Text Messaging as a Tool for Behavior Change in Disease Prevention and Management,” *Epidemiol. Rev.*, vol. 32, no. 1, pp. 56–69, 2010.
[42] S. Krishna, S. A. Boren, and E. A. Balas, “Healthcare via cellphones: A systematic review,” *Telemed. e-Health*, vol. 15, no. 3, pp. 231–240, 2009.
[43] T. Horvath, H. Azman, G. E. Kennedy, and G. W. Rutherford, “Mobile phone text messaging for promoting adherence to antiretroviral therapy in patients with HIV infection,” *Cochrane Database Syst. Rev.*, vol. 3, no. 3, p. CD009756, 2012.
[44] R. T. Lester, P. Ritvo, E. J. Mills, A. Kariri, S. Karanja, M. H. Chung, W. Jack, J. Habyarimana, M. Sadatsafavi, M. Najafzadeh, C. A. Marra, B. Estambale, E. Ngugi, T. B. Ball, L. Thabane, L. J. Gelmon, J. Kimani, M. Ackers, and F. A. Plummer, “Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomised trial,” *Lancet*, vol. 376, no. 9755, pp. 1838–45, 2010.
[45] C. Pop-Eleches, H. Thirumurthy, J. P. Habyarimana, J. G. Zivin, M. P. Goldstein, D. de Walque, L. MacKeen, J. Haberer, S. Kimaiyo, J. Sidle, D. Ngare, and D. R. Bangsberg, “Mobile phone technologies improve adherence to antiretroviral treatment in a resource-limited setting: a randomized controlled trial of text message reminders,” *Aids*, vol. 25, no. 6, pp. 825–834, 2011.
[46] P. Edwards, L. Felix, C. Free, L. Galli, V. Patel, and G. Phillips, “The effectiveness of M-health technologies for improving health and health services: a systematic review protocol,” *BMC Res. Notes*, vol. 3, p. 250, 2010.
[47] V. Flax, M. Negerie, A. Ibrahim, S. Leatherman, E. Daza, and M. Bentley, “Integrating group counseling, cell phone messaging, and participant-generated songs and dramas into a microcredit program increases Nigerian women’s adherence to international breastfeeding recommendations,” *J. Nutr.*, vol. 144, no. 7, pp. 1120–4, 2014.
[48] J. D. Piette and C. A. Mah, “The Feasibility of Automated Voice Messaging as an Adjunct to Diabetes Outpatient Care,” *Diabetes Care*, vol. 20, no. 1, pp. 15–21, Jan. 1997.
[49] A. De Costa, A. Shet, N. Kumarasamy, P. Ashorn, B. Eriksson, L. Bogg, and V. K. Diwan, “Design of a randomized trial to evaluate the influence of mobile phone reminders on adherence to first line antiretroviral treatment in South India - the HIVIND study protocol,” *BMC Med. Res. Methodol.*, vol. 10, no. 25, 2010.
[50] D. Zurovac, R. K. Sudoi, W. S. Akhwale, M. Ndiritu, D. H. Hamer, A. K. Rowe, and R. W. Snow, “The effect of mobile phone text-message reminders on Kenyan health workers’ adherence to malaria treatment guidelines: a cluster randomised trial,” *Lancet*, vol. 378, no. 9793, pp. 795–803, 2011.
[51] M. Van-Velthoven, L. Tudor-Car, S. Gentry, and J. Car, “Telephone delivered interventions for preventing HIV infection in HIV-negative persons,” *Cochrane Libr.*, vol. 5, no. 5, p. CD009190, 2013.

[52] J. Nurmi, “mHealth for health behaviour change Health – the result of personal , interpersonal and environmental factors,” in *m-Health online training course*, 2013, no. April.
[53] M. Fishbein, H. Triandis, E. Kanfer, M. Becker, S. Middlestadt, and A. Eichler, “Factors influencing behavior and behavior change,” in *Handbook of Health Psychology*, A. Baum, T. Revenson, and J. Singer, Eds. New Jersey: Lawrence Earlbaum Associates, 2000.
[54] M. Tomlinson, M. J. Rotheram-Borus, L. Swartz, and A. C. Tsai, “Scaling Up mHealth: Where Is the Evidence?,” *PLoS Med.*, vol. 10, no. 2, pp. 1–5, 2013.
[55] D. Albarracin, B. T. Johnson, M. Fishbein, and P. A. Muellerleile, “Theories of reasoned action and planned behavior as models of common use: a meta-analysis,” *Psychol. Bull.*, vol. 127, no. 1, p. 142, 2001.
[56] P. Sheeran and S. Taylor, “Predicting Intentions to Use Condoms: A Meta-Analysis and Comparison of the Theories of Reasoned Action and Planned Behavior 1,” *J. Appl. Soc. Psychol.*, vol. 29, no. 8, pp. 1624–1675, 1999.
[57] M. N. Nguyen, L. Potvin, and J. Otis, “Regular exercise in 30-to 60-year-old men: Combining the stages-of-change model and the theory of planned behavior to identify determinants for targeting heart health interventions,” *J. Community Health*, vol. 22, no. 4, pp. 233–246, 1997.
[58] N. Corcoran, “Theories and models in communicating health messages,” in *Communicating health: Strategies for health promotion*, 2nd ed., N. Corcoran, Ed. London: SAGE Publications, 2007, pp. 5–31.
[59] R. Schwarzer, D. S. Cao, and S. Lippke, “Stage-matched minimal interventions to enhance physical activity in Chinese adolescents,” *J. Adolesc. Heal.*, vol. 47, pp. 533–539, 2010.
[60] L. Parschau, M. Barz, J. Richert, N. Knoll, S. Lippke, and R. Schwarzer, “Physical Activity among Adults with Obesity: Testing the Health Action Process Approach,” *Rehabil. Psychol.*, vol. 59, pp. 42–49, 2014.
[61] W. Hardeman, M. Johnston, D. Johnston, D. Bonetti, N. Wareham, and A. L. Kinmonth, “Application of the Theory of Planned Behaviour in Behaviour Change Interventions: A Systematic Review,” *Psychol. Health*, vol. 17, no. 2, pp. 123–158, Jan. 2002.
[62] I. Ajzen and M. Fishbein, *Understanding Attitudes and Predicting Social Behavior*. Englewood Cliffs, NJ: Prentice-Hall, 1980.
[63] I. Ajzen, “The theory of planned behavior,” *Organ. Behav. Hum. Decis. Process.*, vol. 50, pp. 179–211, 1991.
[64] K. M. White, N. L. Jimmieson, P. L. Obst, N. Graves, A. Barnett, W. Cockshaw, P. Gee, L. Haneman, K. Page, M. Campbell, E. Martin, and D. Paterson, “Using a theory of planned behaviour framework to explore hand hygiene beliefs at the ‘5 critical moments’ among Australian hospital-based nurses,” *BMC Health Serv. Res.*, vol. 15, p. 59, Feb. 2015.
[65] G. M. Wingood, R. J. DiClemente, S. Arora, A. L. Peters, E. Burner, et. al., “How does the Health Action Process Approach (HAPA) bridge the intention-behavior gap? An examination of the model’s causal structure,” *J. Subst. Abuse Treat.*, vol. 45, no. 1, pp. 1–8, 2014.
[66] S. J. H. Biddle and R. Fuchs, “Exercise psychology: A view from Europe,” *Psychol. Sport Exerc.*, vol. 10, pp. 410–419, 2009.
[67] H. Wilson, M. Sheehan, G. Palk, and A. Watson, “Self-efficacy, planning, and drink driving: Applying the health action process approach.,” *Heal. Psychol.*, vol. 35, no. 7, pp. 695–703, 2016.
[68] S. Sutton, “Stage models of health behaviour,” in *Predicting health behaviour: Research and practice with social cognition models*, 2nd ed., M. Conner and P.

Norman, Eds. Maidenhead, England: Open University Press, 2005, pp. 223–275.
[69] M. Jacobs and A. Graham, “Iterative development and evaluation methods of mHealth behavior change interventions,” *Curr. Opin. Psychol.*, vol. 9, no. June, pp. 33–37, 2015.
[70] M. L. Ybarra, T. L. Prescott, G. L. Philips, S. S. Bull, J. T. Parsons, and B. Mustanski, “Iteratively Developing an mHealth HIV Prevention Program for Sexual Minority Adolescent Men,” *AIDS Behav.*, 2015.
[71] B. C. Bock, R. K. Rosen, N. P. Barnett, H. Thind, K. Walaska, R. Foster, C. Deutsch, and R. Traficante, “Translating Behavioral Interventions Onto mHealth Platforms: Developing Text Message Interventions for Smoking and Alcohol,” *JMIR mHealth uHealth*, vol. 3, no. 1, p. e22, 2015.
[72] M. Hingle, M. Nichter, M. Medeiros, and S. Grace, “Texting for Health: The Use of Participatory Methods to Develop Healthy Lifestyle Messages for Teens,” *J. Nutr. Educ. Behav.*, vol. 45, no. 1, pp. 12–19, 2013.
[73] Statistics South Africa, “South African National Population Census 2011,” Pretoria, 2011.
[74] DEDAT, “Economic Performance Indicators for Cape Town,” Cape Town, 2016.
[75] Statistics South Africa, “Statistical release Quarterly Labour Force Survey,” *Q. Labour Force Surv.*, vol. PO211, no. May, pp. 1–70, 2015.
[76] Western Cape Provisional Treasury, “Municipal Economic Review and Outlook 2016,” Cape Town, 2016.
[77] Statistics South Africa, “Census 2011 - Census in brief,” Pretoria, South Africa, 2012.
[78] Western Cape Government, “Regional Development Profile City of Cape Town Working paper,” pp. 1–75, 2013.
[79] K. Peltzer, S. Ramlagan, B. D. Johnson, and N. Phaswana-Mafuya, “Illicit Drug Use and Treatment in South Africa: A Review,” *Subst. Use Misuse*, vol. 45, no. 13, pp. 2221–2243, 2010.
[80] Y. Toefy, D. Skinner, and S. C. Thomsen, “‘What do You Mean I’ve Got to Wait for Six Weeks?!’ Understanding the Sexual Behaviour of Men and Their Female Partners after Voluntary Medical Male Circumcision in the Western Cape,” *PLoS One*, vol. 10, no. 7, p. e0133156, 2015.
[81] L. Johnson and D. Budlender, “HIV Risk Factors : A Review of the Demographic , Socio-economic , Biomedical and Behavioural Determinants of HIV Prevalence in South Africa,” 2002.
[82] Department of Health (Western Cape), “Western Cape government Health Department’s Annual Report 2014-15,” Cape Town, 2015.
[83] Western Cape Provincial Government, “Provincial Strategic Plan on HIV / AIDS , STIs and TB,” Cape Town, 2012.
[84] Department of Health (Western Cape), “Annual report 2015 - 2016,” Cape Town, 2016.
[85] Clearing house on male circumcision, “Scale-Up of Voluntary Medical Male Circumcision for HIV Prevention in Africa,” 2014.
[86] M. Reicks, C. Smith, H. Henry, K. Reimer, J. Atwell, and R. Thomas, “Use of the Think Aloud Method to Examine Fruit and Vegetable Purchasing Behaviors among Low-Income African American Women,” *J. Nutr. Educ. Behav.*, vol. 35, no. 3, pp. 154–160, 2003.
[87] R. T. Lester, E. J. Mills, A. Kariri, P. Ritvo, M. Chung, W. Jack, J. Habyarimana, S. Karanja, S. Barasa, R. Nguti, B. Estambale, E. Ngugi, T. B. Ball, L. Thabane, J. Kimani, L. Gelmon, M. Ackers, and F. A. Plummer, “The HAART cell phone adherence trial (WelTel Kenya1): a randomized controlled trial protocol,” *Trials*, vol. 10, no. 1, p. 87, 2009.
[88] K. Wools-Kaloustian, S. Kimaiyo, L. Diero, A. Siika, J. Sidle, C. T. Yiannoutsos, B.

Musick, R. Einterz, K. H. Fife, and W. M. Tierney, “Viability and effectiveness of large-scale HIV treatment initiatives in sub-Saharan Africa: experience from western Kenya.,” *AIDS*, vol. 20, no. 1, pp. 41–48, 2006.
[89] S. Thomsen, D. Skinner, Y. Toefy, T. Esterhuizen, M. McCaul, M. Petzold, and V. Diwan, “Voice-Message–Based mHealth Intervention to Reduce Postoperative Penetrative Sex in Recipients of Voluntary Medical Male Circumcision in the Western Cape, South Africa: Randomized Controlled Trial,” *JMIR Res Protoc*.
[90] J. Brooke, “SUS - A quick and dirty usability scale,” *Usability Eval. Ind.*, vol. 189, no. 194, pp. 4–7, 1996.
[91] J. Brooke, “SUS : A Retrospective,” *J. Usability Stud.*, vol. 8, no. 2, pp. 29–40, 2013.
[92] J. R. Lewis and J. Sauro, “The Factor Structure of the System Usability Scale,” in *HCD 09 Proceedings of the 1st International Conference on Human Centered Design: Held as Part of HCI International 2009*, Berlin, 2009, pp. 94–103.
[93] A. Bangor, P. Kortum, and J. Miller, “An empirical evaluation of the System Usability Scale,” *Int. J. Hum. Comput. Interact.*, vol. 24, no. 6, pp. 574–594, 2008.
[94] A. Bangor, P. Kortum, and J. Miller, “Determining what individual SUS scores mean: Adding an adjective rating scale,” *J. usability Stud.*, vol. 4, no. 3, pp. 114–123, 2009.
[95] D. Skinner, “Qualitative research methodology: An introduction,” in *Epidemiology: A Research Manual for South Africa*, 3rd ed., R. Ehrlich and G. Joubert, Eds. Cape Town: Oxford University Press, 2014.
[96] K. Durrheim, M. TerreBlanche, and D. Painter, *Research in Practice: Applied Methods for the Social Sciences*, 2nd ed. Cape Town: University of Cape Town Press, 2010.
[97] IBM, “IBM SPSS Statistics for Windows.” IBM Corporation, Armonk, NY, 2015.
[98] StataCorp, “Stata.” StataCorp, LP, College Station, 2015.
[99] J. M. Grund and M. M. Hennink, “A qualitative study of sexual behavior change and risk compensation following adult male circumcision in urban Swaziland,” *AIDS Care Psychol. Socio-medical Asp. AIDS/HIV*, vol. 24, no. 2, pp. 245–251, 2012.
[100] S. Hartley, “Personal communication, 22 February 2016.” Woodstock Clinic, 2016.
[101] E. Green, *Indigenous Theories of Contagious Disease*. Boston: Rowman Altamira, 2000.
[102] W. Delva, F. Meng, R. Beauclair, N. Deprez, M. Temmerman, A. Welte, and N. Hens, “Coital frequency and condom use in monogamous and concurrent sexual relationships in Cape Town, South Africa,” *J. Int. AIDS Soc.*, vol. 16, no. 1, p. 18034, 2013.
[103] C. D. Jensen, K. M. Duncombe, M. A. Lott, S. L. Hunsaker, K. M. Duraccio, and S. J. Woolford, “An Evaluation of a Smartphone–Assisted Behavioral Weight Control Intervention for Adolescents: Pilot Study,” *JMIR mHealth uHealth*, vol. 4, no. 3, p. e102, Aug. 2016.
[104] A. H. Lichtenstein, “The great fat debate: the importance of message translation,” *J. Am. Dieticians Assoc.*, vol. 111, pp. 667–670, 2011.
[105] A. Antonovsky, “The salutogenic model as a theory to guide health promotion,” *Health Promot. Int.*, vol. 11, no. 1, pp. 11–18, 1996.
[106] M. B. Mittelmark and T. Bull, “The salutogenic model of health in health promotion research.,” *Glob. Health Promot.*, vol. 20, no. 2, pp. 30–8, 2013.
[107] S. J. Czaja, J. Sharit, C. C. Lee, S. N. Nair, M. a Hernández, N. Arana, and S. H. Fu, “Factors influencing use of an e-health website in a community sample of older adults.,” *J. Am. Med. Informatics Assoc.*, vol. 20, no. 2, pp. 277–84, 2013.
[108] V. N. Anney, “Ensuring the quality of the findings of qualitative research: Looking at trustworthiness criteria,” Dar Es Salaam.
[109] E. G. Guba, “Criteria for assessing the trustworthiness of naturalistic inquiries,” *Educ. Commun. Technol. J.*, vol. 29, no. 2, pp. 75–91, 1981.

[110] T. A. Schwandt, Y. S. Lincoln, and E. G. Guba, “Judging interpretations: But is it rigorous? trustworthiness and authenticity in naturalistic evaluation,” *New Dir. Eval.*, vol. 2007, no. 114, pp. 11–25, 2007.
[111] L. Krefting, “Rigor in qualitative research: The assessment of trustworthiness,” *Am. J. Occup. Ther.*, vol. 43, no. 3, p. 214, 1991.
[112] V. Bitsch, “Qualitative research: A grounded theory example and evaluation criteria,” *J. Agribus.*, vol. 23, no. 1, p. 86, 2005.

9 APPENDICES

9.1 APPENDIX ONE: PARTICIPATING MMC CLINICS

No.	Clinic	Sub-Structure	Monthly rate
1.	Bishop Lavis	Northern	Weekly
2.	Delft	Northern	Bi-monthly
3.	Elsies River	Northern	Bi-monthly
4.	Goodwood	Northern	Monthly
5.	Grassy Park	Southern/Central	Bi-monthly
6.	Green Point	Southern/Central	Monthly
7.	Hout Bay	Southern/Central	Monthly
8.	Kensington	Southern/Central	Monthly
9.	Lotus River	Southern/Central	Monthly
10.	Retreat	Southern/Central	Bi-monthly
11.	Vanguard	Southern/Central	Monthly
12.	Woodstock	Southern/Central	Weekly

9.2 APPENDIX TWO: VMMC PRE-SURGERY COUNSELLING PROCEDURES

There are two pre-surgery assessments done with the patient:

- A rapid VCT
- Pre-surgery procedural and post-op wound care talk

9.2.1 The AIDS-Test (Rapid VCT)

Pre-test Counselling session:

The counsellor speaks briefly to the patient on the following topics:

- What his personal history is
- Whether he has any health problems
- What his risk of being HIV infected is
- What he knows about HIV/AIDS
- Information about HIV/AIDS, including the test procedure and what people who are HIV infected can do to make sure that they stay as healthy as possible for as long as possible.
- The advantages and disadvantages for him to having the test
- What kind of support system he has including who he would be able to tell if he tested HIV positive.

Post Test Counselling session:

After giving him his HIV antibody results, the counsellor:

- Allows the patient to express his feeling about being HIV antibody positive, negative or indeterminate. The counsellor then helps the patient to revisit the issues he raised during the pre-test counselling session, including any plans you many have made.
- Discuss any immediate problems and help him to decide on a plan of action
- Answer any questions he may have and provide him with useful information
- Discuss positive living
- Give him positive information on what resources there are in his community to help him.

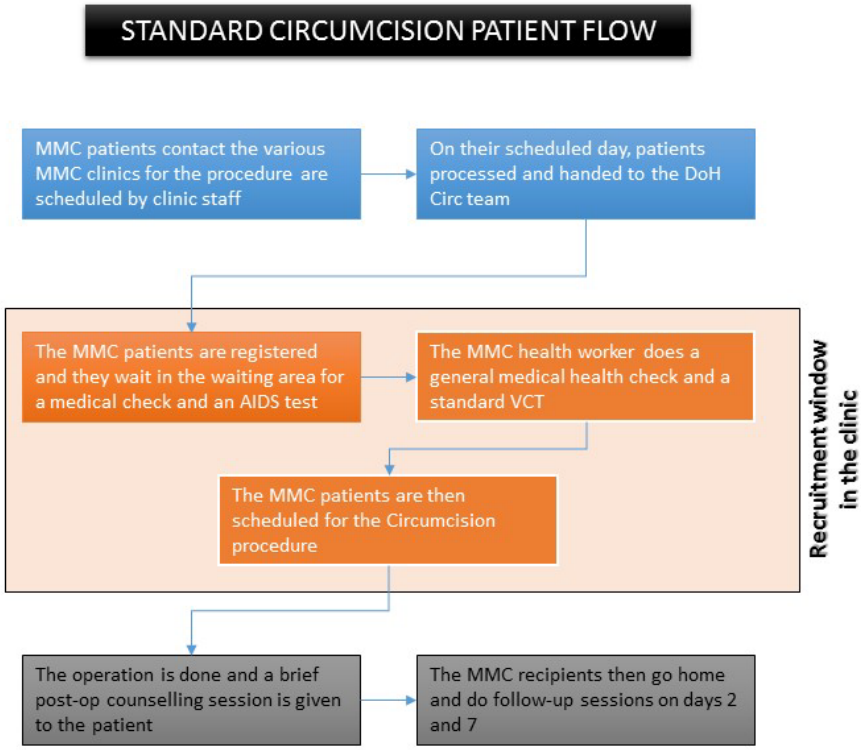
9.3 PRE-SURGERY PROCEDURAL AND POST-OP WOUND CARE TALK

There is some procedural variance between the two circumcision teams in the two municipal sub-structures. The team in the Southern and Western sub-structures has a communal talk with the patients in the waiting room before any surgical procedure start, and the team in the Northern sub-structure does it individually with each patient just before and after the procedure. The issues that are covered are:

- What the actual procedure entail. From the initial injection to the wrapping up of the wound.
- Wound-care management:
    - The strapping of the penis against the body for the next two weeks
    - The importance of follow-up visits on days 2, 7 and 21

- The use of the saline solution to disinfect the wound
- The use of an ice bottle to combat erections
- The emphasis of the no sex/masturbation-rule for 6 weeks
- Pain management and use of medication

9.4 APPENDIX THREE: PATIENT FLOW WITHIN THE MMC CLINIC



9.5 APPENDIX FOUR: INTERVENTION MESSAGES

Day	#	Message
Theme 1: Bi-daily self-care messages from day 1 to day 2		
1	1	Rest! This will help with the wound healing.
	2	Get lots of rest for the next two days. It will help with the healing.
2	3	Go back to the clinic after two and seven days so the dressing can be replaced and the wound can be checked.
	4	You can take a bath a day after the surgery, but don't let the dressing get wet.
Theme 2: Daily self-care messages from day 3 to day 14		
3	5	Use lukewarm water to wash the wound every day. Keep the dressing dry.
4	6	Are you having a difficult time? Talk to someone you love. They will understand.
5	7	Do not pull or scratch the wound while it is healing.
6	8	If there is severe pain and the pain tablets are not helping, contact the clinic.
7	9	If you have difficulty urinating, go see the clinic.
8	10	If there is pus coming out of the wound, go to the clinic.
9	11	If there is a fever within the first week, go to the clinic.
10	12	If there is severe pain in the lower abdomen, go to the clinic.
11	13	Check for any skin tightness when you get an erection.
12	14	Want to be healthy? Look after yourself.
13	15	Bleeding that does not stop is not normal. Go back to the clinic.
14	16	Remember that circumcision does not provide 100% protection
Theme 3: Daily self-care messages from day 15 to day 28		
15	17	Involve your partner in the recovery period
16	18	Think about what you are going to do before you do it
17	19	Don't worry! Just a few weeks more
18	20	Just remember! Having sex before you are ready, will just set you back!
19	21	Take your time when you are pleasing your partner
20	22	Regular exercise and healthy diet are essential
21	23	You can do it!
22	24	Be proud of yourself!
23	25	Having sex too early, will just set you back!
24	26	Get rid of that painful erection by urinating frequently.
25	27	Don't be brave! Take pain tablets to relieve the pain
26	28	Did you look after your penis today?
27	29	No sex or masturbation for six weeks!
28	30	Be aware of alcohol. It impedes your judgement
29	31	Make sure you listen to your partner
30	32	If you have sex before the wound is properly healed, there is a greater chance of contracting STIs or HIV
Theme 4: Tri-weekly self-care messages from day 29 to day 42		
32	33	Loving is not about sex only!
34	34	You did it!
36	35	Start the day with a healthier body in mind
38	36	You don't need your penis to make love
40	37	Show restraint every day, even though it may be difficult. You will be rewarded
42	38	This procedure, with condom use, a knowledge of your HIV status and a reduction in sexual partners is the recipe for an HIV-free future.

9.6 APPENDIX FIVE: THE STUDY PARTICIPANTS OF STUDY I BY SEX AND RELIGION

No.	Gender	Number of Participants	Age Range	Religion (Muslim; Christian)
1	Male	6	19-36	4;2
2	Male	6	22-45	3;3
3	Male	6	23-63	4;2
4	Male	7	18-42	5;2
5	Male	6	20-39	4;2
6	Male	7	21-53	4:3
7	Female	4	22-41	2;2
8	Female	5	19-34	3;2
9	Female	5	25-52	3;2

9.7 APPENDIX SIX: INTERVIEW SCHEDULES OF STUDY I

Interview schedule for VMMC patients

We are here to discuss a particular consideration around your decision be circumcised. We understand that you went through adult circumcision in the last 6 months. As you may be aware, circumcision does provide protection against HIV transmission for the man. But for the immediate period, of up 10 weeks post the operation, the man is actually at increased risk of contracting HIV, and other STDs. We are planning an intervention to try to reduce these risks, but we need to understand what would influence risky behaviour over this time. I am going to ask an initial question and there are areas of specific interest that I want to cover, but I am generally interested in what you have to say.

Why did you decide to get circumcised as an adult, and how was the experience?

- Why did circumcision
- HIV / STD protection
- Expected impact on sex relationship(s)

Experience of circumcision

- Pain during surgery
- Pain since surgery
- Break in sex of 10 weeks
- Counselling and education received
- Complications or problems experienced

Importance of having regular sex

- Relationship
- Feeling like a man
- Have to please partner
- Wanting to test new version of penis

Satisfaction with non-penetrative sex

- Holding and cuddling
- Oral sex
- Mutual masturbation
- Inter thigh sex

Changes in sexual practice

- Any changes in sexual practice since the circumcision

- Use of condoms
- Loss of sensitivity in sex
- Loss in capacity to please partners

Messages for intervention programme

We are planning to use voice messages to provide educational messages on how to men and couples can protect themselves until the wounds have healed.

- Content of messages
- Approach
- Timing of messages
- Information on the circumcision and healing process

Additional sexual partners

- If he has more than one partner, then is the negotiation of sex and safety issues the same with that partner

Interview schedule for partners of VMMC patients

We are here to discuss a particular consideration around your decision be circumcised. We understand that your primary sexual partner went through adult circumcision in the last 6 months. As you may be aware, circumcision does provide protection against HIV transmission for the man. But for the immediate period, of up 10 weeks post the operation, the man is actually at increased risk of contracting HIV, and other STDs. We are planning an intervention to try to reduce these risks, but we need to understand what would influence risky behaviour over this time. I am going to ask an initial question and there are areas of specific interest that I want to cover, but I am generally interested in what you have to say.

Why did he decide to get circumcised as an adult, and how was his experience?

- Why he decided to be circumcised
- HIV / STD protection
- Expected impact on sex relationship(s)

How he described the circumcision

- Pain during surgery
- Pain since surgery
- Break in sex of 10 weeks
- Counselling and education received
- Complications or problems experienced

Importance of having regular sex

- Relationship
- Partner having to feel like a man
- Have to please partner
- Wanting to test new version of penis

Satisfaction with non-penetrative sex

- Holding and cuddling
- Oral sex
- Mutual masturbation
- Inter thigh sex

Changes in sexual practice

- Any changes in sexual practice since the circumcision
- Use of condoms
- Loss of sensitivity in sex
- Loss in capacity to please partners

Messages for intervention programme

We are planning to use voice messages to provide educational messages on how to men and couples can protect themselves until the wounds have healed.

- Content of messages
- Approach
- Timing of messages
- Information on the circumcision and healing process

Additional sexual partners

- If he has more than one partner, then is the negotiation of sex and safety issues the same with that partner

9.8 APPENDIX SEVEN: GENERAL THEMATIC CODE LIST OF STUDY

Reasons

1RSN_HIV protection

1RSN_Cleanliness

1RSN_Religion

1RSN_STI protection

1RSN_Other reasons

1RSN_External v internal LOC

1RSN_Impact on sex

Experience of VMMC

2EXP_Pre-op mx

2EXP_Op procedure

2EXP_Pain during op

2EXP_Pain post-op

2EXP_Sex post-op (10 weeks)

2EXP_Sex post-op (after 10 weeks)

2EXP_Pre- and post-counselling

2EXP_Post-op problems

2EXP_Other

Relationships

3REL_Sex in relationships

3REL_Being a man

3REL_Pleasing partner

3REL_Other partners

3REL_Other

Non-penetrative sex

4ALT_Holding and cuddling

4ALT_Oral sex

4ALT_Masturbation

4ALT_Thigh sex

4ALT_Other

Changes in sexual practices

5SEX_Post-op changes

5SEX_Condoms

5SEX_Sensitivity issue

5SEX_Capacity to please

5SEX_Other

Messages

6MSG_Content

6MSG_Approach

6MSG_Timing

6MSG_Healing mx

6MSG_Cellphone

6MSG_Methods of communication

6MSG_Info on safety

6MSG_Sexual information

6MSG_Info on post-op Tx

6MSG_Other

9.9 APPENDIX EIGHT: DEMOGRAPHICS AND BASELINE CHARACTERISTICS OF RCT PARTICIPANTS

Characteristics	Total	Intervention (n=579)	Control (n=579)
Age of participants (n=1194)			
Age (SD)	29.34 (9.38)	29.78 (9.70)	29.87 (9.04)
18 - 30 yrs	752 (63.0%)	367 (61.5%)	385 (64.5%)
31 – 40 yrs	294 (24.6%)	147 (24.6%)	147 (24.6%)
41 yrs and older	148 (12.4%)	83 (13.9%)	65 (10.9%)
Language (n=1173)			
English	604 (51.5%)	285 (48.7%)	319 (54.3%)
Afrikaans	517 (44.1%)	272 (46.5%)	245 (41.7%)
isiXhosa	38 (3.2%)	24 (4.1%)	14 (2.4%)
Other	14 (1.2%)	4 (0.7%)	10 (1.7%)
Education (n=1161)			
Primary school or less	60 (5.2%)	38 (6.5%)	22 (3.8%)
High School (not completed)	624 (53.7%)	319 (54.9%)	305 (52.6%)
High School (completed)	477 (41.1%)	224 (38.6%)	253 (43.6%)
Post-matric (n=952)	221 (23.2%)	112 (23.8%)	109 (22.6%)
Marital status (n=1176)			
Not married and not living with a partner	619 (52.6%)	296 (50.6%)	323 (54.6%)
Married and not living with a partner	88 (7.5%)	49 (8.4%)	39 (6.6%)
Not married and living with a partner	72 (6.1%)	38 (6.5%)	34 (5.8%)
Married and currently living with partner	223 (19.0%)	112 (19.1%)	112 (19.0%)
Divorced/Widowed	173 (14.7%)	90 (15.4%)	83 (14.1%)
Not living with partner (*v* Living with partner) (n=1176)	881 (74.9%)	436 (74.5%)	445 (75.3%)
Unemployed (*v* Employed) (n=1128)	573 (50.8%)	279 (50.4%)	294 (51.2%)
Religion (n=1172)			
Formal Churches	479(62.3%)	235(63.9%)	244(60.84%)
Charismatic Churches	106(13.8%)	51(13.9%)	55(13.7%)
Muslim	167(21.7%)	78(21.2%)	89(22.2%)
Other	17(2.2%)	4(1.1%)	13(3.2%)
Type of dwelling (n=1144)			
Homeless or shack dweller	150 (13.1%)	81 (14.2%)	69 (12.0%)
Room in hostel or garage	100 (8.7%)	49 (8.6%)	51 (8.9%)
Flat or house	894 (78.1%)	441 (77.2%)	453 (79.1%)
Told you have an STI at Baseline(n=1118)	196 (17.5%)	111 (19.8%)	85 (15.3%)
Self-reported HIV positive status at post evaluation	87 (9.70%)	43 (9.70%)	44 (9.70%)

CPT_CIRC STUDY

Version: 19062015_03_YT

Loss to Follow Up: Phone Survey (Form P8)

Hello,
My name is _____ and I am calling on behalf of a study conducted by Stellenbosch University. As you may recall, you agreed to participate in a study in the time following your circumcision and since you were unable to come to your six-week follow up appointment with us, I am calling to gather some post-operation information from you. As is with all elements of this study, your responses are confidential and completely anonymous. It is only eleven short questions and should only take a few minutes. Are you willing to participate?

No	Question	Response			
1	Since your circumcision, have you been diagnosed with a sexually transmitted disease (STD)?	Yes	No		
2	Based on your behavior over the past 6 weeks are circumcision, how much do you think you are at risk for getting HIV?	Not at risk	A little bit at risk	Somewhat at risk	Very much at risk
3	Since your circumcision, on average, how many days a week have you felt depressed?	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of the time (3-4 days)	Most or all of the time (5-7 days)
4	Since your circumcision have you felt more nervous and anxious than usual?	A little of the time	Some of the time	A good part of the time	Most of the time
5	In the last two weeks of the recovery period (weeks 4-6) did you experience any pain or swelling of your penis?	Yes	No	Refuse to Answer	
6	Since your circumcision, has your sexual partner lived with you?	Yes	No	Refuse to Answer	
7	Since your circumcision, have you had penetrative sex (with your penis) **without** a condom?	Yes	No	Refuse to Answer	
8	Since your circumcision, have you had penetrative sex (with your penis) **with** a condom?	Yes	No	Refuse to Answer	
9	***(If respondent answered yes to question 7and/or 8)*** When was the first time you had penetrative sex following your circumcision?	Within the first three weeks after surgery	In the fourth week after surgery	In the fifth week after surgery	In the sixth week after surgery
10	Did you receive audio messages following your circumcision?	Yes	No		
11	***(If respondent answered yes to question 10)*** How would you rate the following statement: I found this system very cumbersome to use	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree
12	***(If respondent answered yes to question 10)*** How would you rate the following statement: I feel very confident using this system	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree

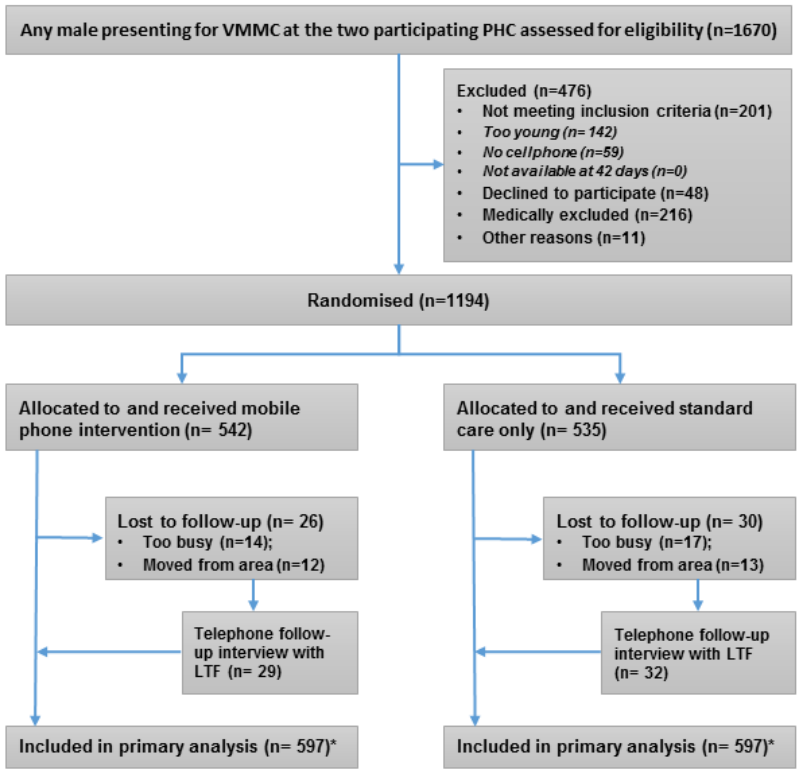
***(At the completion of the survey)**: That is all the questions I have for you. Thank you for your time and cooperation.*

Study Number:	Date completed:	Interviewer:	Captured:

9.11 APPENDIX TEN: DEMOGRAPHIC DETAILS OF FOLLOWED-UP AND LOSS TO FOLLOW-UP

Variables	Levels	Completed (1138)	Loss to follow-up (56)	p-value
Age categories of participants	18 - 30	715 (62.8%)	37 (66.1%)	0.874
	31 - 40	281 (24.7%)	13 (23.2%)	
	41 and older	142 (12.5%)	6 (10.7%)	
Language spoken	Afrikaans	492 (43.3%)	25 (44.6%)	0.717
	English	575 (50.6%)	29 (51.8%)	
	isiXhosa	38 (3.3%)	0 (0.0%)	
	Other	13 (1.1%)	1 (1.8%)	
Schooling levels	Primary school or less	59 (5.3%)	1 (1.8%)	0.490*
	High School (not completed)	592 (53.6%)	32 (57.1%)	
	High School (completed)	454 (41.1%)	23 (41.1%)	
Religious affiliation	Formal Churches	462 (63.2%)	17 (44.7%)	0.021*
	Charismatic Chuches	100 (13.7%)	6 (15.8%)	
	Muslim	155 (21.2%)	12 (31.6%)	
	Other	14 (1.9%)	3 (7.9%)	
Cohabiting status	Not living with partner	711 (75.2%)	36 (75.0%)	0.980
	Living with partner	235 (24.8%)	12 (25.0%)	

9.12 APPENDIX ELEVEN: CONSORT DIAGRAM OF THE RCT STUDY



* Intention-to-treat design, so all participants included in analysis

9.13 APPENDIX TWELVE: DEMOGRAPHIC DETAILS OF PARTICIPANTS WHO AGREED TO PARTICIPATE AND THOSE WHO DID NOT

Variables	Levels	Assented to participate (1194)	Declined to participate (48)	p-value
Age categories of participants	18 - 30	752 (58.3%)	28 (63.0%)	0.430
	31 - 40	294 (22.9%)	11 (24.6%)	
	41 and older	148 (18.8%)	9 (12.4%)	
Language spoken	Afrikaans	517 (43.3%)	21 (43.6%)	0.798
	English	604 (50.6%)	26 (54.8%)	
	isiXhosa	38 (3.3%)	1 (2.1%)	
	Other	13 (1.1%)	1 (1.8%)	
Schooling levels	Primary school or less	60 (5.2%)	4 (10.0%)	0.401
	High School (not completed)	624 (53.7%)	21 (52.5%)	
	High School (completed)	477 (41.1%)	15 (37.5%)	
Religious affiliation	Formal Churches	479 (62.3%)	15 (31.3%)	0.093
	Charismatic Chuches	106 (13.8%)	9 (18.8%)	
	Muslim	167 (21.7%)	19 (39.9%)	
	Other	17 (2.2%)	5 (10.4%)	
Cohabiting status	Not living with partner	747 (75.2%)	32 (72.9%)	0.674
	Living with partner	247 (24.8%)	16 (27.1%)	

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